EPA REGISTRATION NUMBER 524-339

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

OCT - 6 2003

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

Mr. Stephen J. Wratten
Monsanto Company
600 13th Street, N. W. , Suite 660
Washington, DC 2005

Dear Mr. Wratten:

Subject: Exchange Herbicide (Update First Aid Statement and Other Changes)
EPA Registration No. 524-339
Application Dated July 7, 2003

The labeling referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended is acceptable provide your make the following changes.

–Under Storage and Disposal revise "Storage" to read "Pesticide Storage" and "Disposal" to read "Pesticide Disposal".--

Submit three (3) copies of your final printed labeling incorporating the above changes. Amended labeling will supercede all previously accepted ones. A stamped copy of labeling is enclosed for your records.

Sincerely,

Vicki K Walton for
James A Tompkins
Product Manager 25
Herbicide Branch
Registration Division (7505C)

Exchange Herbicide

PRECAUTIONARY STATEMENTS

Hazards to Humans and Domestic Animals

Keep out of reach of children.

DANGER!

CAUSES IRREVERSIBLE EYE DAMAGE. HARMFUL IF SWALLOWED OR INHALED. MAY CAUSE SKIN IRRITATION. Do not get in eyes, on skin or on clothing. Wear goggles or face shield. Avoid breathing vapor or spray mist. Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash contaminated clothing before reuse.

First Aid: Call a poison control center or doctor for treatment advice.	
IF IN EYES	Hold eye open and rinse slowly and gently with water for 15 - 20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye.
IF ON SKIN	Take off contaminated clothing. Rinse skin immediately with plenty of water for 15 – 20 minutes.
IF SWALLOWED	Have person sip a glass of water if able to swallow. Do not induce vomiting unless told to do so by the poison control center or doctor. Do not give anything by mouth to an unconscious person.
IF INHALED	Move person to fresh air. If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably by mouth-to-mouth if possible.
Have the product container or label with you when calling a poison control center or doctor, or going for treatment. This product is identified as **Exchange Herbicide, EPA Reg. No. 524-339.** You may also contact (314) 694-4000, call collect day or night for emergency treatment information.	
NOTE TO PHYSICIAN: Probable mucosal damage may contraindicate the use of gastric lavage.	

Environmental Hazards

Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans or other waters unless in accordance with the requirements of a National Pollution Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to the discharge. Do not discharge effluent containing this product into sewer systems without previously notifying the sewage treatment plant authority. For guidance, contact your State Water Board or Regional Office of the EPA.

Physical or Chemical Hazards

Solutions of this product should be mixed and stored using only stainless steel, aluminum, fiberglass, plastic and plastic-lined containers.

DO NOT MIX, STORE OR UTILIZE THIS PRODUCT OR SOLUTIONS OF THIS PRODUCT IN GALVANIZED STEEL OR UNLINED STEEL (EXCEPT STAINLESS STEEL) CONTAINERS OR TANKS. This product or solutions of this product react with such containers and tanks to produce hydrogen gas which may form a highly combustible gas mixture. This gas mixture could flash or explode, causing serious personal injury, if ignited by open flame, spark, welder's torch, lighted cigarette or other ignition source.

In case of: SPILL or LEAK, soak up and remove to a landfill.

DIRECTIONS FOR USE

Read entire label before using this product.

It is a violation of Federal law to use this product in any manner inconsistent with its labeling.

Use only for manufacturing, formulating, or repackaging into a herbicide for use in aquatic, industrial, turf, ornamental nursery, tree and forestry, and residential sites; or some or all of the following food cropping systems: root, bulb, and tuber vegetables, leafy vegetables, brassica and cucurbit vegetables, succulent and dried legume vegetables, fruiting vegetables, fruits (citrus, pome, stone, various tropical fruits, small fruits and berries), tree nuts, cereal grains, animal grasses and forages, herbs, spices, and food crops including asparagus, avocado, banana, canola, coffee, cotton, coconut, cranberry, dates, flax, grapes, kiwi, lychee, mints, olive, palms, peanut, pineapple, soybeans, strawberry, sugar beet, sugarcane, and tea.

Storage and Disposal

STORAGE: Do not contaminate water, foodstuffs, feed or seed by storage or disposal. Keep container closed to prevent spills and contamination.

DISPOSAL: Wastes of this product may cause irreversible eye damage and may be dangerous. Improper disposal of excess pesticide or rinsate is a violation of Federal law. If these wastes cannot be disposed of by use according to the label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance.

Emptied container retains vapor and product residue.

Observe all labeled safeguards until container is cleaned, reconditioned or destroyed.

Triple rinse emptied container. Then offer for recycling or reconditioning, or dispose of in a manner approved by state and local authorities.

ACTIVE INGREDIENT:	
*Glyphosate, in the form of its isopropylamine salt	41.0%
OTHER INGREDIENTS:	59.0%
	100.0%

*Contains 480 grams per liter or 4 pounds per U.S. gallon of the active ingredient glyphosate, in the form of its isopropylamine salt. Equivalent to 356 grams per liter or 3 pounds per U.S. gallon of the acid glyphosate.

LIMIT OF WARRANTY AND LIABILITY

Monsanto Company does not warrant any product reformulated or repackaged from this product except in accordance with this Company's stewardship requirements and with express written permission from Monsanto Company.

EPA Reg. No. 524-339

Exchange is a trademark of Monsanto Technology LLC.

EPA Est. 524-LA-1 ☐ 524-IA-1 ☐ LOT NO. PACKER NET lb.

ACCEPTED
with COMMENTS
In EPA Letter Dated:
OCT - 6 2003
Under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, for the pesticide registered under EPA Reg. No. 524-339

[print plate]

3

G | 1 | 5 | 2 | 4 | • | 1 | 1 | 3 | 3 | 9 | 1 | 0 | 1 | 7 | 1 | 0 | 3

3. IS A PUBLIC DATA SHEET NECESSARY? ☐ YES ☐ NO	4. PETITION NO.		5. RECEIVED ON TERM: MO. DAY YR.	
6. METHOD OF SUPPORT ☐ EA ☐ IR ☐ IC	7. PRODUCT MANAGER	NO.	8. PROJECTED RETURN: MO. DAY YR.	
9. DATE PULLED: 9/30/03	10. DATE PUBLISHED: AWP	11. ACTION TYPE: Update Fint and alter Charges 300	CODE	12. OUTGOING DATE: MO. DAY YR.

REVIEW SEQUENCE	REVIEW CODE	REVIEW TYPE	REVIEWER CODE (Initials)	SIGNATURE OF REVIEWER	COMMENT CODE	DATE REVIEW COMPLETED: MO.	DAY	YR.
	A	REVIEWABILITY TEAM						
	B	PRODUCT MANAGER TEAM EFFICACY REVIEW						
	C	PRODUCT MANAGER TEAM HUMAN SAFETY REVIEW						
	D	PRODUCT MANAGER TEAM ENVIRONMENTAL SAFETY REVIEW						
	E	PRODUCT MANAGER TEAM RECONSIDERATION REVIEW						
	F	PRODUCT MANAGER		VKW	RL	09	30	03
	G	INTERAGENCY REFERRAL		Pesticide Storage				
	H	COST-BENEFIT REVIEW		Pesticide Disposal				
	I	PUBLIC COMMENTS REVIEW						
	J	EEB BRANCH INSECTICIDE EFFICACY						
	K	EEB BRANCH HERBICIDE EFFICACY						
	L	EEB BRANCH FUNGICIDE EFFICACY						
	M	EEB BRANCH BIOCENTICIDE EFFICACY						
	N	EEB BRANCH DISINFECTANT EFFICACY						
	O	CHEMISTRY BRANCH HERBICIDE CHEMISTRY						
	P	EEB BRANCH ENVIRON. + MENTAL CHEMISTRY						
	Q	TOXICOLOGY BRANCH HUMAN SAFETY						
	R	EEB BRANCH ENVIRON. MENTAL SAFETY						
	S							
	T							

PRODUCT MANAGER SIGNATURE	TYPE OF RESPONSE	CODE

EPA Form 8570-13 (5-72)

Please read instructions on reverse before completing form. Form Approved. OMB No. 2070-0060

EPA

United States
Environmental Protection Agency
Washington, DC 20460

☐ Registration
☒ Amendment
☐ Other

OPP Identifier Number
296721

Application for Pesticide - Section I

1. Company/Product Number
Monsanto / 524-339

2. EPA Product Manager
Mr. James Tompkins

3. Proposed Classification
☒ None ☐ Restricted

4. Company/Product (Name)
Exchange Herbicide

PM#
25

5. Name and Address of Applicant *(Include ZIP Code)*
Monsanto Company
600 13th Street, N.W., Suite 660
Washington, DC 20005

☐ *Check if this is a new address*

6. **Expedited Review.** In accordance with FIFRA Section 3(c)(3)(b)(i), my product is similar or identical in composition and labeling to:
EPA Reg. No. _____
Product Name _____

Section - II

● Amendment - Explain below.
☐ Resubmission in response to Agency letter dated _____
☐ Notification - Explain below.
☐ Final printed labels in response to Agency letter dated _____
☐ "Me Too" Application.
☐ Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

Modify First Aid per PR Notice 2001-1
Update DFU Statements

Section - III

1. Material This Product Will Be Packaged In:

Child-Resistant Packaging
☐ Yes*
● No
** Certification must be submitted*

Unit Packaging
☐ Yes
☐ No
If "Yes" Unit Packaging wgt. / No. per container

Water Soluble Packaging
☐ Yes
☐ No
If "Yes" Package wgt / No. per container

2. Type of Container
☐ Metal
☐ Plastic
☐ Glass
☐ Paper
☐ Other (Specify) _____

3. Location of Net Contents Information
☐ Label ☐ Container

4. Size(s) Retail Container

5. Location of Label Directions
☐ On Label
☐ On Labeling accompanying product

6. Manner in Which Label is Affixed to Product
☐ Lithograph
☐ Paper glued
☐ Stenciled
☐ Other _____

Section - IV

1. Contact Point *(Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)*

Name	Title	Telephone No. (Include Area Code)
Dr. Marsha Gray	Registration Manager	(202) 783-2460

Certification

I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

6. Date Application Received (Stamped)

2. Signature Stephen J. Wratten

3. Title
Manager, Registrations

4. Typed Name
Stephen J. Wratten, Ph.D.

5. Date
July 7, 2003

EPA Form 8570-1 (Rev. 8-94) Previous editions are obsolete. White - EPA File Copy (original) Yellow - Applicant Copy

PAPERWORK REDUCTION ACT NOTICE and INSTRUCTIONS

PAPERWORK REDUCTION ACT NOTICE: Public reporting burden for this collection of information is estimated to average 0.85 hour per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to Chief, Information Policy Branch, (2136), U.S. Environmental Protection Agency, 401 M Street, SW, Washington, DC 20460.

INSTRUCTIONS: This form is to be used for all applications for new registration, and use reregistration, amendment, resubmission, to applications for notifications, final printed labeling, reregistration, etc. In order to process an application for a new registration submitted on this form, the following material must accompany the application:

1. Certification with Respect to Citation of Data (EPA Form 8570-29). [If not exempted by 40 CFR 152.81 (b) (4)];
2. Confidential Statement of Formula (EPA Form 8570-4);
3. Formulator's Exemption Statement (EPA Form 8570-27);
4. Five copies of draft labeling;
5. Three copies of any data submitted;
6. Authorization letter where applicable;
7. Matrices where applicable.

Submission of Labeling - Labeling should first be submitted in the form of draft labels with all applications for new registration. Such draft labels may be in the form of typed label text on 8.5 x 11 inch paper for submission or a mockup of the proposed label. If prepared for mockup, it should be constructed in a way as to facilitate storage in an 8.5 x 11 inch file. Mockup labels significantly smaller than 8.5 x 11 inches should be mounted on 8.5 x 11 inch paper for submission.
Submission of Data - Data submitted in support of this application must be submitted in accordance with PR Notice 86-5.

SPECIFIC INSTRUCTIONS: Please read the instructions listed below before completing this application. First determine the type of registration action, listed in Block A, for which you are submitting this application. For applications submitted in connection with New Registration actions, Sections I, III, and IV must be completed by the applicant. For applications submitted in connection with amended reregistration actions, resubmissions, notifications, reregistrations, etc., Sections I, II, and IV must be completed by the applicant.
Block A - Check the appropriate action for which you are submitting this form.

SECTION I - This section must be completed, as applicable, for all registration actions.

1. Company/Product Number - Insert your Company Number, if one has been assigned by EPA. This number may have been assigned to you as a basic registrant, a distributor, or as an establishment. If your product is registered, insert the Product Number.
2. EPA Product Manager - If known, fill in the name and PM number of the EPA Product Manager.
3. Proposed Classification - Specify the proposed classification of this product.
4. Product Name - Enter the complete product name of this pesticide as it will appear on the label. The name must be specific to this product only. Duplication of names is not permitted among products of the same company. Do not include any brand name or company line designations.
5. Name and Address of Applicant - The name of the firm or person and address shown in your application is the person or firm to whom the registration will be issued. If you are acting in behalf of another party, you must submit authorization from that party to act for them in registration matters. An applicant not residing in the United States must have an authorized agent residing in the United States to act for them in all registration matters. The name and complete mailing address of such an agent must accompany this application.
6. Expedited Review - FIFRA section 3 (c) 3 (B) provides for expedited review of applications for registration, or amendments to existing registrations that are similar or identical to other pesticide products that are currently registered with the EPA. In order for your application to be eligible for expedited review, you must provide us with the EPA Registration Number and product name of the product you believe is similar to or identical to your product. The product must be similar or identical in both formulation and labeled uses.

SECTION II - This section must be completed for all applications submitted to amend the registration only of a currently registered product (Amendment), for a resubmission in response to an Agency letter, for notifications to the Agency, for the submission of final printed labeling, for reregistration and for any other action that pertains to a specific EPA-registered product. This section is not to be used for a new application for registration.

1. Subject of submission - Check the applicable block and provide the Agency letter date if appropriate. Provide a brief explanation of the purpose(s) for the submission, such as "the addition of a site, pest or crop (specify)"; "amend the Confidential Statement of Formula by..."; "reregistration submission"; "general label revision of use directions." Attach a separate page if additional space is needed.

SECTION III (Packaging and Container Information) - This Section must be completed for all applications submitted in connection with new registration or applicable amendments.

1. Type of Packaging - Check the appropriate block if your product will be packaged in the indicated packaging types. Indicate the size of the individual packets and number per retail container.
2. Type of Retail Container - Indicate type of container in which product will be marketed.
3. Location of Net Contents - Indicate the location of the net contents information for your product.
4. Size(s) of Retail Container - Specify the net contents of all retail containers for your product.
5. Location of Use Directions - Indicate the location of the use directions for your product.
6. Manner in which label is affixed to product - Indicated the method product label is attached to retail container.

SECTION IV (Contact Point) - This Section must be completed for all applications for Registration actions, i.e., new products registration, resubmission, "me-too," reregistration, etc.

1-5. Self-explanatory.
6. EPA Use Only.

MONSANTO

MONSANTO COMPANY
600 13TH STREET, N.W.
SUITE 660
WASHINGTON, D.C. 20005
http://www.monsanto.com

July 7, 2003

Document Processing Center (AMEND)
Office of Pesticide Programs (7504C)
U. S. Environmental Protection Agency
Room 266A, Crystal Mall #2
1921 Jefferson Davis Highway
Arlington, VA 22202-4501

Attention: Mr. James A. Tompkins
Team Leader (25)

Subject: **Exchange Herbicide (EPA Reg. No. 524-339)**
Modify First Aid per PR Notice 2001-1
Update DFU statements

Dear Mr. Tompkins:

Monsanto has begun a project to ensure that all of our active manufacturing use product labels are compliant with the First Aid formatting specified in PRN 2001-1. We have also taken this opportunity to update the paragraph in the Directions for Use section that lists approved use sites, and to ensure that the storage and disposal statements are sensible and consistent with modern practices. Enclosed are 5 copies of draft labeling for Exchange Herbicide for your review and approval.

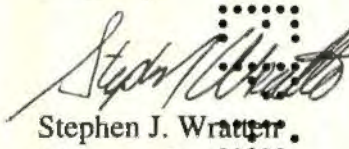
The label for this product was last approved on 15-Apr-1999, and the following changes are herein proposed. They will apply also to Shackle C Herbicide, an alternate brand name on this registration:

- No changes are proposed in the Precautionary Statements, other than reformatting the First Aid.

- Some minor word changes are proposed for the Physical Hazards section, so as to conform exactly to wording used on other Monsanto glyphosate MUPs.
- Standard Instructions for Spill or Leak were added.
- The list of use sites in the DFU section is proposed to be consistent with that approved for MON 0139 Technical Solution (524-333) on 15-Aug-2002, and includes specific mention of key crops such as soybeans, cotton, and canola.
- The ingredient statement for "glyphosate" was shortened, consistent with PR Notice 97-5, which indicates that no additional chemical name is necessary with such well-known active ingredients.
- The disposal statement "do not reuse this container" was deleted, since this product may be distributed in plastic containers that can be reconditioned.
- Patents have expired on this product, and are no longer mentioned.

If you have any questions on this matter please feel free to contact me through Dr. Marsha C. Gray (202-383-2878) or by direct phone (314-694-1582), fax (314-694-4028), or electronic mail at stephen.j.wratten@monsanto.com.

Sincerely,



Stephen J. Wratten
Manager, Registrations

cc: M. C. Gray

Exchange First Aid.doc

16 B 14-2

Please read instructions on reverse before completing form. Form Approved. OMB No. 2070-0060

EPA

United States
Environmental Protection Agency
Washington, DC 20460

☐ Registration
☐ Amendment
☒ Other

OPP Identifier Number: 267971

Application for Pesticide - Section I

1. Company/Product Number: 524-339

2. EPA Product Manager: Mr. James Tompkins

3. Proposed Classification: ☒ None ☐ Restricted

4. Company/Product (Name): Exchange Herbicide

PM# 25

5. Name and Address of Applicant *(Include ZIP Code)*
Monsanto Company
600 13th Street, N.W., Suite 660
Washington, DC 20005

☐ *Check if this is a new address*

6. **Expedited Review.** In accordance with FIFRA Section 3(c)(3)(b)(i), my product is similar or identical in composition and labeling to:
EPA Reg. No. _____
Product Name _____

Section - II

☐ Amendment - Explain below.
● Resubmission in response to Agency letter dated _____
☐ Notification - Explain below.
☒ Final printed labels in response to Agency letter dated NOTIFICATION 15 Apr 1999
☐ "Me Too" Application.
☐ Other - Explain below.

JAN 19 2000

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

Section - III

1. Material This Product Will Be Packaged In:

Child-Resistant Packaging	Unit Packaging	Water Soluble Packaging	2. Type of Container
☐ Yes* ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Metal ☐ Plastic ☐ Glass ☐ Paper ☐ Other (Specify) _____
*Certification must be submitted	If "Yes" Unit Packaging wgt. / No. per container	If "Yes" Package wgt / No. per container	

3. Location of Net Contents Information: ☐ Label ☐ Container

4. Size(s) Retail Container

5. Location of Label Directions: ☐ On Label ☐ On Labeling accompanying product

6. Manner in Which Label is Affixed to Product: ☐ Lithograph ☐ Paper glued ☐ Stenciled ☐ Other _____

Section - IV

1. Contact Point *(Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)*

Name	Title	Telephone No. (Include Area Code)
Dr. Russell P. Schneider	Agricultural Regulation Director	(202) 783-2460

Certification

I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

6. Date Application Received (Stamped)

2. Signature	3. Title	4. Typed Name	5. Date
Stephen J. Wratten	Manager, Registrations	Stephen J. Wratten, Ph.D.	December 21, 1999

EPA Form 8570-1 (Rev. 8-94) Previous editions are obsolete. White - EPA File Copy (original) Yellow - Applicant Copy

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1-5. Self-explanatory.
6. EPA Use Only.

MONSANTO

Food · Health · Hope™

MONSANTO COMPANY
600 13TH STREET, N.W.
SUITE 660
WASHINGTON, D.C. 20005
TEL: (202) 783-2460
FAX: (202) 783-2468

December 21, 1999

Hand Delivered

Office of Pesticide Programs
Document Processing Center (NOTIF)
U. S. Environmental Protection Agency
Room 266A, Crystal Mall #2
1921 Jefferson Davis Highway
Arlington, VA 22202

Attention: Mr. James A. Tompkins (7505C)
Team Leader (25)

Subject: Exchange Herbicide (EPA Reg. No. 524-339)
Final Printed Labeling
Responsive to 15-Apr-1999 approval

Dear Mr. Tompkins:

On 15-Apr-1999, the Agency approved updated language for the manufacturing products registered as EPA Reg. No. 524-339. These include Exchange ®, Shackle ® C, and MON 78087 brand names. Enclosed are the final printed labels arising from this approval for Exchange, identified as Print Plate 21006W2-2/53L. The only difference between the printed and approved text is the inclusion of the word "Discharge", which had been inadvertently omitted from the NPDES sentence in the draft text.

If you have any questions on this matter please feel free to contact me through Dr. Russell P. Schneider (202-383-2866) or by direct phone (314-694-1582), fax (314-694-4028), or electronic mail at stephen.j.wratten@monsanto.com.

Sincerely,

Stephen J. Wratten
Manager, Registrations

cc: R. P. Schneider

EXCHANGE®

Herbicide by Monsanto

PRECAUTIONARY STATEMENTS

Hazards to Humans and Domestic Animals

Keep out of reach of children.

DANGER!

CAUSES IRREVERSIBLE EYE DAMAGE.

HARMFUL IF SWALLOWED OR INHALED.

MAY CAUSE SKIN IRRITATION.

Do not get in eyes, on skin or on clothing.

Wear goggles or face shield.

Avoid breathing vapor or spray mist.

Wash thoroughly with soap and water after handling.

Remove contaminated clothing and wash before reuse.

FIRST AID: IF IN EYES, immediately flush with plenty of water for at least 15 minutes. Get medical attention.

If ON SKIN, immediately flush with plenty of water. Remove contaminated clothing. Wash clothing before reuse.

IF SWALLOWED, this product will cause gastrointestinal tract irritation. Immediately dilute by swallowing water or milk. Get medical attention.

NOTE TO PHYSICIAN: Probable mucosal damage may contraindicate the use of gastric lavage.

IF INHALED, remove individual to fresh air. Get medical attention if breathing difficulty develops.

In case of an emergency involving this product,
Call Collect, day or night, (314) 694-4000.

Environmental Hazards

Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA.

Physical or Chemical Hazards

Solutions of this product should be mixed and stored using only stainless steel, aluminum, fiberglass, plastic or plastic-lined steel containers.

DO NOT MIX OR STORE THIS PRODUCT OR SOLUTIONS OF THIS PRODUCT IN GALVANIZED OR UNLINED STEEL (EXCEPT STAINLESS STEEL) CONTAINERS. This product or solutions of this product react with such containers and tanks to produce hydrogen gas which may form a highly combustible gas mixture. This gas could flash or explode, causing serious personal injury, if ignited by open flame, spark, welder's torch, lighted cigarette or other ignition source.

DIRECTIONS FOR USE

Read the entire label before using this product.

It is a violation of Federal law to use this product in any manner inconsistent with its labeling.

This product may only be reformulated or repackaged into a herbicide for use in industrial, turf, and ornamental sites; residential sites; or some or all of the following cropping systems: vegetables, citrus, pome fruits, stone fruits, small fruits and berries, tree nuts, cereal grains, animal grasses and forages, tropical fruits, asparagus, avocado, banana, cotton, cranberry, fig, grapes, kiwi, mango, okra, papaya, peanut, persimmon, pineapple, sugarcane and watercress.

Storage and Disposal

Do not contaminate water, foodstuffs, feed or seed by storage or disposal.

DISPOSAL: Wastes of this product may cause irreversible eye damage and may be dangerous. Improper disposal of excess pesticide or rinsate is a violation of Federal law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance.

Emptied container retains vapor and product residue. Observe all labeled safeguards until container is destroyed.

Do not reuse container. Triple rinse container. Then puncture and dispose of in a sanitary landfill, or by incineration, or, if allowed by state and local authorities, by burning. If burned, stay out of smoke.

ACTIVE INGREDIENT:	
*Glyphosate, N-(phosphonomethyl)glycine, in the form of its isopropylamine salt	41.0%
OTHER INGREDIENTS:	59.0%
	100.0%

*Contains 480 grams per litre or 4 pounds per U.S. Gallon of the active ingredient glyphosate, in the form of its isopropylamine salt. Equivalent to 356 grams per litre or 3 pounds per U.S. gallon of the acid, glyphosate.

LIMIT OF WARRANTY AND LIABILITY

Monsanto Company does not warrant any product reformulated or repackaged from this product except in accordance with this Company's stewardship requirements and with express written permission from Monsanto Company.

EPA Reg. No. 524-339

EPA Est. 524-LA-1 21006W2-2/53L

NET 54 U.S. GAL.

(01) 0 00 70183 50409 1

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MONSANTO
Food · Health · Hope™

MONSANTO COMPANY
600 13TH STREET, N.W.
SUITE 660
WASHINGTON, D.C. 20005
TEL: (202) 783-2460
FAX: (202) 783-2468

January 5, 2000

Hand Delivered

Office of Pesticide Programs
Document Processing Center (NOTIF)
U. S. Environmental Protection Agency
Room 266A, Crystal Mall #2
1921 Jefferson Davis Highway
Arlington, VA 22202

Attention: Mr. James A. Tompkins (7505C)
Team Leader (25)

Subject: MON 78087 Herbicide (EPA Reg. No. 524-339)
Final Printed Labeling
Responsive to 15-Apr-1999 approval

Dear Mr. Tompkins:

On 15-Apr-1999, the Agency approved updated language for the manufacturing products registered as EPA Reg. No. 524-339. These include Exchange ®, Shackle ® C, and MON 78087 brand names. Enclosed are the final printed labels arising from this approval for MON 78087, identified as Print Plate 21167X2-1/53M.

If you have any questions on this matter please feel free to contact me through Dr. Russell P. Schneider (202-383-2866) or by direct phone (314-694-1582), fax (314-694-4028), or electronic mail at stephen.j.wratten@monsanto.com.

Sincerely,

Stephen J. Wratten
Manager, Registrations

cc: R. P. Schneider

Please read instructions on reverse before completing form. Form Approved. OMB No. 2070-0060

EPA

United States
Environmental Protection Agency
Washington, DC 20460

☐ Registration
☐ Amendment
☒ Other

OPP Identifier Number: 267974

Application for Pesticide - Section I

1. Company/Product Number: 524-339

2. EPA Product Manager: Mr. James Tompkins

3. Proposed Classification: ☒ None ☐ Restricted

4. Company/Product (Name): MON 78087 Herbicide

PM#: 25

5. Name and Address of Applicant *(Include ZIP Code)*

Monsanto Company
600 13th Street, N.W., Suite 660
Washington, DC 20005

☐ *Check if this is a new address*

6. **Expedited Review.** In accordance with FIFRA Section 3(c)(3)(b)(i), my product is similar or identical in composition and labeling to:

EPA Reg. No. _____

Product Name _____

Section - II

☐ Amendment - Explain below.

☐ Resubmission in response to Agency letter dated _____

☐ Notification - Explain below.

☒ Final printed labels in response to Agency letter dated 15-Apr-1999

☐ "Me Too" Application.

☐ Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

Section - III

1. Material This Product Will Be Packaged In:

Child-Resistant Packaging	Unit Packaging	Water Soluble Packaging	2. Type of Container
☐ Yes* ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Metal ☐ Plastic ☐ Glass ☐ Paper ☐ Other (Specify) _____
* *Certification must be submitted*	If "Yes" Unit Packaging wgt. / No. per container	If "Yes" Package wgt / No. per container	

3. Location of Net Contents Information: ☐ Label ☐ Container

4. Size(s) Retail Container

5. Location of Label Directions: ☐ On Label ☐ On Labeling accompanying product

6. Manner in Which Label is Affixed to Product: ☐ Lithograph ☐ Paper glued ☐ Stenciled ☐ Other _____

Section - IV

1. Contact Point *(Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)*

Name	Title	Telephone No. (Include Area Code)
Dr. Russell P. Schneider	Agricultural Regulation Director	(202) 783-2460

Certification

I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

6. Date Application Received (Stamped)

2. Signature: Stephen J. Wratten

3. Title: Manager, Registrations

4. Typed Name: Stephen J. Wratten, Ph.D.

5. Date: January 5, 2000

EPA Form 8570-1 (Rev. 8-94) Previous editions are obsolete. White - EPA File Copy (original) Yellow - Applicant Copy

PAPERWORK REDUCTION ACT NOTICE and INSTRUCTIONS

PAPERWORK REDUCTION ACT NOTICE: Public reporting burden for this collection of information is estimated to average 0.85 hour per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to Chief, Information Policy Branch, (2136), U.S. Environmental Protection Agency, 401 M Street, SW, Washington, DC 20460.

INSTRUCTIONS: This form is to be used for all applications for new registration, end use reregistration, amendment, resubmission, to applications for notifications, final printed labeling, reregistration, etc. In order to process an application for a new registration submitted on this form, the following material must accompany the application:

1. Certification with Respect to Citation of Data (EPA Form 8570-29). [If not exempted by 40 CFR 152.81 (b) (4)];
2. Confidential Statement of Formula (EPA Form 8570-4);
3. Formulator's Exemption Statement (EPA Form 8570-27);
4. Five copies of draft labeling;
5. Three copies of any data submitted;
6. Authorization letter where applicable;
7. Matrices where applicable.

Submission of Labeling - Labeling should first be submitted in the form of draft labels with all applications for new registration. Such draft labels may be in the form of typed label text on 8.5 x 11 inch paper for submission or a mockup of the proposed label. If prepared for mockup, it should be constructed in a way as to facilitate storage in an 8.5 x 11 inch file. Mockup labels significantly smaller than 8.5 x 11 inches should be mounted on x 11 inch paper for submission.
Submission of Data - Data submitted in support of this application must be submitted in accordance with PR Notice 86-5.

SPECIFIC INSTRUCTIONS: Please read the instructions listed below before completing this application. First determine the type of registration action, listed in Block A, for which you are submitting this application. For applications submitted in connection with New Registration actions, Sections I, III, and IV must be completed by the applicant. For applications submitted in connection with amended reregistration actions, resubmissions, notifications, reregistrations, etc., Sections I, II, and IV must be completed by the applicant.
Block A - Check the appropriate action for which you are submitting this form.

SECTION I - This section must be completed, as applicable, for all registration actions.

1. Company/Product Number - Insert your Company Number, if one has been assigned by EPA. This number may have been assigned to you as a basic registrant, a distributor, or as an establishment. If your product is registered, insert the Product Number.
2. EPA Product Manager - If known, fill in the name and PM number of the EPA Product Manager.
3. Proposed Classification - Specify the proposed classification of this product.
4. Product Name - Enter the complete product name of this pesticide as it will appear on the label. The name must be specific to this product only. Duplication of names is not permitted among products of the same company. Do not include any brand name or company line designations.
5. Name and Address of Applicant - The name of the firm or person and address shown in your application is the person or firm to whom the registration will be issued. If you are acting in behalf of another party, you must submit authorization from that party to act for them in registration matters. An applicant not residing in the United States must have an authorized agent residing in the United States to act for them in all registration matters. The name and complete mailing address of such an agent must accompany this application.
6. Expedited Review - FIFRA section 3 (c) 3 (B) provides for expedited review of applications for registration, or amendments to existing registrations, that are similar or identical to other pesticide products that are currently registered with the EPA. In order for your application to be eligible for expedited review, you must provide us with the EPA Registration Number and product name of the product you believe is similar to or identical to your product. The product must be similar or identical in both formulation and labeled uses.

SECTION II - This section must be completed for all applications submitted to amend the registration only of a currently registered product (Amendment), for a resubmission in response to an Agency letter, for notifications to the Agency, for the submission of final printed labeling, for reregistration and for any other action that pertains to a specific EPA-registered product. This section is not to be used for a new application for registration.

1. Subject of submission - Check the applicable block and provide the Agency letter date if appropriate. Provide a brief explanation of the purpose(s) for the submission, such as "the addition of a site, pest or crop (specify)"; "amend the Confidential Statement of Formula by..."; "reregistration submission"; "general label revision of use directions." Attach a separate page if additional space is needed.

SECTION III (Packaging and Container Information) - This Section must be completed for all applications submitted in connection with new registration or applicable amendments.

1. Type of Packaging - Check the appropriate block if your product will be packaged in the indicated packaging types. Indicate the size of the individual packets and number per retail container.
2. Type of Retail Container - Indicate type of container in which product will be marketed.
3. Location of Net Contents - Indicate the location of the net contents information for your product.
4. Size(s) of Retail Container - Specify the net contents of all retail containers for your product.
5. Location of Use Directions - Indicate the location of the use directions for your product.
6. Manner in which label is affixed to product - Indicated the method product label is attached to retail container.

SECTION IV (Contact Point) - This Section must be completed for all applications for Registration actions, i.e., new products registration, resubmission, "me-too," reregistration, etc.

1-5. Self-explanatory.
6. EPA Use Only.

MON 78087

Herbicide by Monsanto

PRECAUTIONARY STATEMENTS

Hazards to Humans and Domestic Animals

Keep out of reach of children.

DANGER!

CAUSES IRREVERSIBLE EYE DAMAGE.
HARMFUL IF SWALLOWED OR INHALED.
MAY CAUSE SKIN IRRITATION.
Do not get in eyes, on skin or on clothing.
Avoid breathing vapor or spray mist.

FIRST AID: IF IN EYES, immediately flush with plenty of water for at least 15 minutes. Get medical attention. **IF ON SKIN,** immediately flush with plenty of water. **IF SWALLOWED,** this product will cause gastrointestinal tract irritation. Immediately dilute by swallowing water or milk. Get medical attention. **NOTE TO PHYSICIAN:** Probable mucosal damage may contraindicate the use of gastric lavage. **IF INHALED,** remove individual to fresh air. Get medical attention if breathing difficulty develops.

In case of an emergency involving this product,
Call Collect, day or night, (314) 694-4000.

Environmental Hazards

Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA.

Physical or Chemical Hazards

Solutions of this product should be mixed and stored using only stainless steel, aluminum, fiberglass, plastic or plastic-lined steel containers.

DO NOT MIX OR STORE THIS PRODUCT OR SOLUTIONS OF THIS PRODUCT IN GALVANIZED OR UNLINED STEEL (EXCEPT STAINLESS STEEL) CONTAINERS. This product or solutions of this product react with such containers and tanks to produce hydrogen gas which may form a highly combustible gas mixture. This gas could flash or explode, causing serious personal injury, if ignited by open flame, spark, welder's torch, lighted cigarette or other ignition source.

DIRECTIONS FOR USE

Read the entire label before using this product.
It is a violation of Federal law to use this product in any manner inconsistent with its labeling.
This product may only be reformulated or repackaged into a herbicide for use in industrial, turf, and ornamental sites; residential sites; or some or all of the following cropping systems; vegetables, citrus, pome fruits, stone fruits, small fruits and berries, tree nuts, cereal grains, animal grasses and forages, tropical fruits, asparagus, avocado, banana, cotton, cranberry, fig, grapes, kiwi, mango okra, papaya, peanut, persimmon, pineapple, sugarcane and watercress.

Storage and Disposal

Do not contaminate water, foodstuffs, feed or seed by storage or disposal.

DISPOSAL: Wastes of this product may cause irreversible eye damage and may be dangerous. Improper disposal of excess pesticide or rinsate is a violation of Federal law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance.

Emptied container retains vapor and product residue. Observe all labeled safeguards until container is cleaned, reconditioned, or destroyed.

Triple rinse emptied bulk container. Then offer for recycling or reconditioning, or dispose of in a manner approved by state and local authorities.

ACTIVE INGREDIENT:

*Glyphosate, N-(phosphonomethyl)glycine, in the form of its isopropylamine salt	41.0%
OTHER INGREDIENTS:	59.0%
	100.0%

*Equivalent to 356 grams per litre or 3 pounds per U.S. gallon of the acid, glyphosate.

This product is protected by U.S. Patent No. 4,405,531. Other patents pending. No license granted under any non-U.S. patents.

LIMIT OF WARRANTY AND LIABILITY

Monsanto Company does not warrant any product reformulated or repackaged from this product except in accordance with the Company's stewardship requirements and with express written permission from Monsanto Company.

EPA Reg. No. 524-339

NOT REVIEWED
In Accordance with PR Notice 87-2.
Based on Draft Labeling Dated 4/15/99

LOT NO. PACKER NET GAL.

EPA Est. 524-IA-1

21167X2-1/53M

B

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MONSANTO COMPANY
600 13TH STREET, N.W.
SUITE 660
WASHINGTON, D.C. 20005
TEL: (202) 783-2460
FAX: (202) 783-2468

January 5, 2000

Hand Delivered

Office of Pesticide Programs
Document Processing Center (NOTIF)
U. S. Environmental Protection Agency
Room 266A, Crystal Mall #2
1921 Jefferson Davis Highway
Arlington, VA 22202

Attention: Mr. James A. Tompkins (7505C)
Team Leader (25)

Subject: Shackle® C Herbicide (EPA Reg. No. 524-339)
Final Printed Labeling
Responsive to 15-Apr-1999 approval

Dear Mr. Tompkins:

On 15-Apr-1999, the Agency approved updated language for the manufacturing products registered as EPA Reg. No. 524-339. These include Exchange ®Herbicide, Shackle ® C Herbicide, and MON 78087 brand names. Enclosed are the final printed labels arising from this approval for Shackle C, identified as Print Plate 21074W2-1FT.

If you have any questions on this matter please feel free to contact me through Dr. Russell P. Schneider (202-383-2866) or by direct phone (314-694-1582), fax (314-694-4028), or electronic mail at stephen.j.wratten@monsanto.com.

Sincerely,

Stephen J. Wratten
Manager, Registrations

cc: R. P. Schneider

Please read instructions on reverse before completing form. Form Approved. OMB No. 2070-0060

EPA

United States
Environmental Protection Agency
Washington, DC 20460

☐ Registration
☐ Amendment
☒ Other

OPP Identifier Number
267975

Application for Pesticide - Section I

1. Company/Product Number	2. EPA Product Manager	3. Proposed Classification
524-339	Mr. James Tompkins	☒ None ☐ Restricted
4. Company/Product (Name) Shackle C Herbicide	PM# 25	

5. Name and Address of Applicant *(Include ZIP Code)*
Monsanto Company
600 13th Street, N.W., Suite 660
Washington, DC 20005

☐ *Check if this is a new address*

6. **Expedited Review.** In accordance with FIFRA Section 3(c)(3)(b)(i), my product is similar or identical in composition and labeling to:
EPA Reg. No. _____
Product Name _____

Section - II

- ☐ Amendment - Explain below.
- ☐ Resubmission in response to Agency letter dated _____
- ☐ Notification - Explain below.
- ☒ Final printed labels in response to Agency letter dated 15-Apr-1999
- ☐ "Me Too" Application.
- ☐ Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

Section - III

1. Material This Product Will Be Packaged In:

Child-Resistant Packaging	Unit Packaging	Water Soluble Packaging	2. Type of Container
☐ Yes* ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Metal ☐ Plastic ☐ Glass ☐ Paper ☐ Other (Specify)
* *Certification must be submitted*	If "Yes" Unit Packaging wgt. / No. per container	If "Yes" Package wgt / No. per container	

3. Location of Net Contents Information	4. Size(s) Retail Container	5. Location of Label Directions
☐ Label ☐ Container		☐ On Label ☐ On Labeling accompanying product

6. Manner in Which Label is Affixed to Product ☐ Lithograph ☐ Paper glued ☐ Stenciled ☐ Other _____

Section - IV

1. Contact Point *(Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)*

Name	Title	Telephone No. (Include Area Code)
Dr. Russell P. Schneider	Agricultural Regulation Director	(202) 783-2460

Certification

I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

2. Signature	3. Title	6. Date Application Received (Stamped)
Stephen Wratten	Manager, Registrations	
4. Typed Name Stephen J. Wratten, Ph.D.	5. Date January 5, 2000	

EPA Form 8570-1 (Rev. 8-94) Previous editions are obsolete. White - EPA File Copy (original) Yellow - Applicant Copy

PAPERWORK REDUCTION ACT NOTICE and INSTRUCTIONS

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INSTRUCTIONS: This form is to be used for all applications for new registration, end use reregistration, amendment, resubmission, to applications for notifications, final printed labeling, reregistration, etc. In order to process an application for a new registration submitted on this form, the following material must accompany the application:

1. Certification with Respect to Citation of Data (EPA Form 8570-29). [If not exempted by 40 CFR 152.81 (b) (4)];
2. Confidential Statement of Formula (EPA Form 8570-4);
3. Formulator's Exemption Statement (EPA Form 8570-27);
4. Five copies of draft labeling;
5. Three copies of any data submitted;
6. Authorization letter where applicable;
7. Matrices where applicable.

Submission of Labeling - Labeling should first be submitted in the form of draft labels with all applications for new registration. Such draft labels may be in the form of typed label text on 8.5 x 11 inch paper for submission or a mockup of the proposed label. If prepared for mockup, it should be constructed in a way as to facilitate storage in an 8.5 x 11 inch file. Mockup labels significantly smaller than 8.5 x 11 inches should be mounted on x 11 inch paper for submission.
Submission of Data - Data submitted in support of this application must be submitted in accordance with PR Notice 86-5.

SPECIFIC INSTRUCTIONS: Please read the instructions listed below before completing this application. First determine the type of registration action, listed in Block A, for which you are submitting this application. For applications submitted in connection with New Registration actions, Sections I, III, and IV must be completed by the applicant. For applications submitted in connection with amended reregistration actions, resubmissions, notifications, reregistrations, etc., Sections I, II, and IV must be completed by the applicant.
Block A - Check the appropriate action for which you are submitting this form.

SECTION I - This section must be completed, as applicable, for all registration actions.

1. Company/Product Number - Insert your Company Number, if one has been assigned by EPA. This number may have been assigned to you as a basic registrant, a distributor, or as an establishment. If your product is registered, insert the Product Number.
2. EPA Product Manager - If known, fill in the name and PM number of the EPA Product Manager.
3. Proposed Classification - Specify the proposed classification of this product.
4. Product Name - Enter the complete product name of this pesticide as it will appear on the label. The name must be specific to this product only. Duplication of names is not permitted among products of the same company. Do not include any brand name or company line designations.
5. Name and Address of Applicant - The name of the firm or person and address shown in your application is the person or firm to whom the registration will be issued. If you are acting in behalf of another party, you must submit authorization from that party to act for them in registration matters. An applicant not residing in the United States must have an authorized agent residing in the United States to act for them in all registration matters. The name and complete mailing address of such an agent must accompany this application.
6. Expedited Review - FIFRA section 3 (c) 3 (B) provides for expedited review of applications for registration, or amendments to existing registrations, that are similar or identical to other pesticide products that are currently registered with the EPA. In order for your application to be eligible for expedited review, you must provide us with the EPA Registration Number and product name of the product you believe is similar to or identical to your product. The product must be similar or identical in both formulation and labeled uses.

SECTION II - This section must be completed for all applications submitted to amend the registration only of a currently registered product (Amendment), for a resubmission in response to an Agency letter, for notifications to the Agency, for the submission of final printed labeling, for reregistration and for any other action that pertains to a specific EPA-registered product. This section is not to be used for a new application for registration.

1. Subject of submission - Check the applicable block and provide the Agency letter date if appropriate. Provide a brief explanation of the purpose(s) for the submission, such as "the addition of a site, pest or crop (specify)"; "amend the Confidential Statement of Formula by..."; "reregistration submission"; "general label revision of use directions." Attach a separate page if additional space is needed.

SECTION III (Packaging and Container Information) - This Section must be completed for all applications submitted in connection with new registration or applicable amendments.

1. Type of Packaging - Check the appropriate block if your product will be packaged in the indicated packaging types. Indicate the size of the individual packets and number per retail container.
2. Type of Retail Container - Indicate type of container in which product will be marketed.
3. Location of Net Contents - Indicate the location of the net contents information for your product.
4. Size(s) of Retail Container - Specify the net contents of all retail containers for your product.
5. Location of Use Directions - Indicate the location of the use directions for your product.
6. Manner in which label is affixed to product - Indicated the method product label is attached to retail container.

SECTION IV (Contact Point) - This Section must be completed for all applications for Registration actions, i.e., new products registration, resubmission, "me-too," reregistration, etc.

1-5. Self-explanatory.
6. EPA Use Only.

CONCENTRATE

SHACKLE® C

Herbicide by Monsanto

NOT REVIEWED
In Accordance with PR Notice 8[illegible]
Based on Draft Labeling Dated 4/16/99

PRECAUTIONARY STATEMENTS

Hazards to Humans and Domestic Animals

Keep out of reach of children.

DANGER!

CAUSES IRREVERSIBLE EYE DAMAGE. HARMFUL IF SWALLOWED OR INHALED. MAY CAUSE SKIN IRRITATION.

Do not get in eyes, on skin or on clothing. Wear goggles or face shield. Avoid breathing vapor or spray mist. Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash before reuse.

FIRST AID: IF IN EYES, immediately flush with plenty of water for at least 15 minutes. Get medical attention. **If ON SKIN,** immediately flush with plenty of water. Remove contaminated clothing. Wash clothing before reuse. **IF SWALLOWED,** this product will cause gastrointestinal tract irritation. Immediately dilute by swallowing water or milk. Get medical attention. NOTE TO PHYSICIAN: Probable mucosal damage may contraindicate the use of gastric lavage. **IF INHALED,** remove individual to fresh air. Get medical attention if breathing difficulty develops.

In case of an emergency involving this product,
Call Collect, day or night, (314) 694-4000.

Environmental Hazards

Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans or other public waters unless in accordance with the requirements of a National Pollutant Discharge Elimination Systems (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage tretment plant authority. For guidance contact your State Water Board or Regional Office of the EPA.

Physical or Chemical Hazards

Solutions of this product should be mixed and stored using only stainless steel, aluminum, fiberglass, plastic and plastic-lined steel containers. DO NOT MIX OR STORE THIS PRODUCT OR SOLUTIONS OF THIS PRODUCT IN GALVANIZED OR UNLINED STEEL (EXCEPT STAINLESS STEEL) CONTAINERS. This product or solutions of this product react with such containers and tanks to produce hydrogen gas which may form a highly combustible gas mixture. This gas could flash or explode, causing serious personal injury, if ignited by open flame, spark, welder's torch, lighted cigarette or other ignition source.

DIRECTIONS FOR USE

Read the entire label before using this product.

It is a violation of Federal law to use this product in any manner inconsistent with its labeling.

This product may only be reformulated or repackaged into a herbicide (not to exceed 10% active ingredient) for use in industrial, turf, and ornamental sites; residential sites; or some or all of the following cropping systems: vegetables, citrus, pome fruits, stone fruits, small fruits and berries, tree nuts, cereal grains, animal grasses and forages, tropical fruits, asparagus, avocado, banana, cotton, cranberry, fig, grapes, kiwi, mango, okra, papaya, peanut, persimmon, pineapple, sugarcane and watercress.

Storage and Disposal

Do not contaminate water, foodstuffs, feed or seed by storage or disposal.

DISPOSAL: Wastes of this product may cause irreversible eye damage and may be dangerous. Improper disposal of excess pesticide or rinsate is a violation of Federal law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance.

Emptied container retains vapor and product residue. Observe all labeled safeguards until container is cleaned, reconditioned, or destroyed.

Do not reuse container. Triple rinse container. Then puncture and dispose of in a sanitary landfill, or by incineration, or, if allowed by state and local authorities, by burning. If burned, stay out of smoke.

FOR HERBICIDE FORMULATION ONLY

ACTIVE INGREDIENT:	
*Glyphosate, N-(phosphonomethyl)glycine, in the form of its isopropylamine salt.	41.0%
OTHER INGREDIENTS:	59.0%
	100.0%

*Contains 480 grams per litre or 4 pounds per U.S. Gallon of the active ingredient glyphosate, in the form of its isopropylamine salt. Equivalent to 356 grams per litre or 3 pounds per U.S. gallon of the acid, glyphosate.

This product is protected by U.S. Patent No. 4,405,531. Other patents pending. No license granted under any non-U.S. patent(s).

LIMIT OF WARRANTY AND LIABILITY

Monsanto Company does not warrant any product reformulated or repackaged from this product except in accordance with this Company's stewardship requirements and with express written permission from Monsanto Company.

Shackle is a registered trademark of Monsanto Company.

EPA Reg. No. 524-339

21

LOT NO. PACKER NET U.S. GAL.

EPA Est. 239-IA-3

21074W2-1FT

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

APR 15 1999

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

Dr. Stephen J. Wratten
Monsanto Company
600 13th Street, NW, Suite 660
Washington, DC 20005

Dear Dr. Wratten:

Subject: MON 78087 Herbicide (Update Label Text)
EPA Registration No. 524-339
Your Application Dated February 5, 1999

The labeling referred to above, submitted in connection with connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended is acceptable. Please submit three(3) copies of your final printed labeling before you release the product for shipment. A stamped copy of labeling is enclosed for your records.

Sincerely,

Victoria C Walters for
James A. Tompkins
Product Manager 25
Herbicide Branch
Registration Division (7505C)

MON 78087

Herbicide by Monsanto

PRECAUTIONARY STATEMENTS

Hazards to Humans and Domestic Animals

Keep out of reach of children.

DANGER!

CAUSES IRREVERSIBLE EYE DAMAGE.
HARMFUL IF SWALLOWED OR INHALED.
MAY CAUSE SKIN IRRITATION.
Do not get in eyes, on skin or on clothing.
Avoid breathing vapor or spray mist.

FIRST AID: IF IN EYES, immediately flush with plenty of water for at least 15 minutes. Get medical attention. **IF ON SKIN,** immediately flush with plenty of water. **IF SWALLOWED,** this product will cause gastrointestinal tract irritation. Immediately dilute by swallowing water or milk. Get medical attention. **NOTE TO PHYSICIAN:** Probable mucosal damage may contraindicate the use of gastric lavage. **IF INHALED,** remove individual to fresh air. Get medical attention if breathing difficulty develops.

In case of an emergency involving this product, Call Collect, day or night, (314) 694-4000.

Environmental Hazards

Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA.

Physical or Chemical Hazards

Solutions of this product should be mixed and stored using only stainless steel, aluminum, fiberglass, plastic or plastic-lined steel containers.

DO NOT MIX OR STORE THIS PRODUCT OR SOLUTIONS OF THIS PRODUCT IN GALVANIZED OR UNLINED STEEL (EXCEPT STAINLESS STEEL) CONTAINERS. This product or solutions of this product react with such containers and tanks to produce hydrogen gas which may form a highly combustible gas mixture. This gas could flash or explode, causing serious personal injury, if ignited by open flame, spark, welder's torch, lighted cigarette or other ignition source.

DIRECTIONS FOR USE

Read the entire label before using this product.
It is a violation of Federal law to use this product in any manner inconsistent with its labeling.
This product may only be reformulated or repackaged into a herbicide for use in industrial, turf, and ornamental sites; residential sites; or some or all of the following cropping systems; vegetables, citrus, pome fruits, stone fruits, small fruits and berries, tree nuts, cereal grains, animal grasses and forages, tropical fruits, asparagus, avocado, banana, cotton, cranberry, fig, grapes, kiwi, mango okra, papaya, peanut, persimmon, pineapple, sugarcane and watercress.

Storage and Disposal

Do not contaminate water, foodstuffs, feed or seed by storage or disposal.

DISPOSAL: Wastes of this product may cause irreversible eye damage and may be dangerous. Improper disposal of excess pesticide or rinsate is a violation of Federal law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance.

Emptied container retains vapor and product residue. Observe all labeled safeguards until container is cleaned reconditioned, or destroyed.

Triple rinse emptied bulk container. Then offer for recycling or reconditioning, or dispose of in a manner approved by state and local authorities.

ACTIVE INGREDIENT:	
*Glyphosate, N-(phosphonomethyl)glycine, in the form of its isopropylamine salt	41.0%
OTHER INGREDIENTS:	59.0%
	100.0%

*Equivalent to 356 grams per litre or 3 pounds per U.S. gallon of the acid, glyphosate.

This product is protected by U.S. Patent No. 4,405,531. Other patents pending. No license granted under any non-U.S. patents.

LIMIT OF WARRANTY AND LIABILITY

Monsanto Company does not warrant any product reformulated or repackaged from this product except in accordance with the Company's stewardship requirements and with express written permission from Monsanto Company.

EPA Reg. No. 524-339

LOT NO. PACKER NET GAL.

EPA Est. 524-IA-1

21167X2-1/53M

1. SUBMISSION OR REG. NO.		2. DATE RECEIVED (MO / DAY / YR)
G 524-339		02 08 99

3. [illegible]	4. PETITION NO.	5. RECEIVED BY TEAM (MO / DAY / YR)
☐ YES ☐ NO		

6. METHOD OF SUPPORT	7. PRODUCT MANAGER	NO.	8. PROJECTED RETURN (MO / DAY / YR)
☐ ☐ ☐			

9. DATE PULLED	10. DATE PUBLISHED	11. ACTION TYPE	CODE	12. OUTGOING DATE (MO / DAY / YR)
4/13/99		MON 78087 Herbicide Update Label Text 300		

	REVIEW TYPE	REVIEWER CODE (Initials)	SIGNATURE OF REVIEWER	COMMENT CODE	DATE REVIEW COMPLETED MO	DAY	YR
A	REVIEWABILITY TEAM						
B	PRODUCT MANAGER TEAM EFFICACY REVIEW						
C	PRODUCT MANAGER TEAM HUMAN SAFETY REVIEW						
D	PRODUCT MANAGER TEAM ENVIRONMENTAL SAFETY REVIEW						
E	PRODUCT MANAGER TEAM RESUBMISSION REVIEW						
F	PRODUCT MANAGER		VKW	VAC	04	13	99
G	INTERAGENCY REFERRAL						
H	COST-BENEFIT REVIEW						
I	PUBLIC COMMENTS REVIEW						
J	EEE BRANCH INSECTICIDE EFFICACY						
K	EEE BRANCH HERBICIDE EFFICACY						
L	EEE BRANCH FUNGICIDE EFFICACY						
M	EEE BRANCH RODENTICIDE EFFICACY						
N	EEE BRANCH DISINFECTANT EFFICACY						
O	CHEMISTRY BRANCH RESIDUE CHEMISTRY						
P	EEE BRANCH ENVIRONMENTAL CHEMISTRY						
Q	TOXICOLOGY BRANCH HUMAN SAFETY						
R	EEE BRANCH ENVIRONMENTAL SAFETY						
S							
T							

PRODUCT MANAGER SIGNATURE	TYPE OF RESPONSE	CODE

EPA Form 8570-13 (3-75)

A

B

MONSANTO

Food • Health • Hope™

MONSANTO COMPANY
600 13TH STREET, N.W.
SUITE 660
WASHINGTON, D.C. 20005
TEL: (202) 783-2460
FAX: (202) 783-2468

February 5, 1999

Hand Delivered

Office of Pesticide Programs
Document Processing Center (AMEND)
U. S. Environmental Protection Agency
Room 266A, Crystal Mall #2
1921 Jefferson Davis Highway
Arlington, VA 22202

Attention: Mr. James A. Tompkins (7505C)
Team Leader (25)

Subject: **MON 78087 Herbicide (EPA Reg. No. 524-339)**
Update Label Text

Dear Mr. Tompkins:

On 4-Nov-1998, Monsanto notified EPA that we would use a new brand name "MON 78087 Herbicide" on EPA Reg. No. 524-339 for the purpose of bulk shipments of Manufacturing Use product intended for export. Final printed labeling for use in 1999 was submitted on 14-Jan-1999.

Although the labeling as submitted was not incorrect, certain aspects of that text were inconsistent with other labels on that registration number, such as Exchange Herbicide. In particular, formatting derived from the WPS was included, as were references to application, weed control, and spray solutions, and spray tanks. These references are not needed on a Manufacturing Use product. As part of our label stewardship program, we have been reviewing our Manufacturing Use Product labels for consistency and updating them as needed.

We now propose to replace the earlier MON 78087 Herbicide label with the enclosed text, which is identical to that proposed 22-Jan-1999 for Exchange Herbicide. Five (5) copies are enclosed for EPA review and approval.

If you have any questions on this matter please feel free to contact me through Dr. Russell P. Schneider or directly at 314-694-1582.

Sincerely,

Stephen J. Wratten
Manager, Registrations

cc: R. P. Schneider
D. Fee-White

A B

Please read instructions on reverse before completing form.

Form Approved. OMB No. 2070-0060. Approval expires 05-31-98

United States
Environmental Protection Agency
Washington, DC 20460

☐ Registration
☒ Amendment
☐ Other

OPP Identifier Number: 250900

Application for Pesticide - Section I

1. Company/Product Number	2. EPA Product Manager	3. Proposed Classification
524-339	Mr. James Tompkins	☒ None ☐ Restricted
4. Company/Product (Name)	PM#	
MON 78087 Herbicide	25	

5. Name and Address of Applicant *(Include ZIP Code)*
Monsanto Company
600 13th Street, N.W., Suite 660
Washington, DC 20005

☐ *Check if this is a new address*

6. **Expedited Review.** In accordance with FIFRA Section 3(c)(3)(b)(i), my product is similar or identical in composition and labeling to:
EPA Reg. No. _____
Product Name _____

Section - II

☒ Amendment - Explain below.
☐ Resubmission in response to Agency letter dated _____
☐ Notification - Explain below.
☐ Final printed labels in response to Agency letter dated _____
☐ "Me Too" Application.
☐ Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

Update label text

Section - III

1. Material This Product Will Be Packaged In:

Child-Resistant Packaging	Unit Packaging	Water Soluble Packaging	2. Type of Container
☐ Yes* ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Metal ☐ Plastic ☐ Glass ☐ Paper ☐ Other (Specify)
* *Certification must be submitted*	If "Yes" Unit Packaging wgt. / No. per container	If "Yes" Package wgt / No. per container	

3. Location of Net Contents Information	4. Size(s) Retail Container	5. Location of Label Directions
☐ Label ☐ Container		☐ On Label ☐ On Labeling accompanying product

6. Manner in Which Label is Affixed to Product ☐ Lithograph ☐ Paper glued ☐ Stenciled ☐ Other _____

Section - IV

1. Contact Point *(Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)*

Name	Title	Telephone No. (Include Area Code)
Dr. Russell Schneider	Agricultural Regulation Director	(202) 783-2460

Certification

I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

2. Signature	3. Title	6. Date Application Received (Stamped)
Stephen J. Wratten	Manager, Registrations	
4. Typed Name: Stephen J. Wratten, Ph.D.	5. Date: February 5, 1999	

EPA Form 8570-1 (Rev. 8-94) Previous editions are obsolete. White - EPA File Copy (original) Yellow - Applicant Copy

PAPERWORK REDUCTION ACT NOTICE and INSTRUCTIONS

PAPERWORK REDUCTION ACT NOTICE: Public reporting burden for this collection of information is estimated to average 0.85 hour per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to Chief, Information Policy Branch, (2136), U.S. Environmental Protection Agency, 401 M Street, SW, Washington, DC 20460.

INSTRUCTIONS: This form is to be used for all applications for new registration, end use reregistration, amendment, resubmission, to applications for notifications, final printed labeling, reregistration, etc. In order to process an application for a new registration submitted on this form, the following material must accompany the application:

1. Certification with Respect to Citation of Data (EPA Form 8570-29). [If not exempted by 40 CFR 152.81 (b) (4)];
2. Confidential Statement of Formula (EPA Form 8570-4);
3. Formulator's Exemption Statement (EPA Form 8570-27);
4. Five copies of draft labeling;
5. Three copies of any data submitted;
6. Authorization letter where applicable;
7. Matrices where applicable.

Submission of Labeling - Labeling should first be submitted in the form of draft labels with all applications for new registration. Such draft labels may be in the form of typed label text on 8.5 x 11 inch paper for submission or a mockup of the proposed label. If prepared for mockup, it should be constructed in a way as to facilitate storage in an 8.5 x 11 inch file. Mockup labels significantly smaller than 8.5 x 11 inches should be mounted on 8.5 x 11 inch paper for submission.

Submission of Data - Data submitted in support of this application must be submitted in accordance with PR Notice 86-5.

SPECIFIC INSTRUCTIONS: Please read the instructions listed below before completing this application. First determine the type of registration action, listed in Block A, for which you are submitting this application. For applications submitted in connection with New Registration actions, Sections I, III, and IV must be completed by the applicant. For applications submitted in connection with amended reregistration actions, resubmissions, notifications, reregistrations, etc., Sections I, II, and IV must be completed by the applicant.

Block A - Check the appropriate action for which you are submitting this form.

SECTION I - This section must be completed, as applicable, for all registration actions.

1. **Company/Product Number** - Insert your Company Number, if one has been assigned by EPA. This number may have been assigned to you as a basic registrant, a distributor, or as an establishment. If your product is registered, insert the Product Number.
2. **EPA Product Manager** - If known, fill in the name and PM number of the EPA Product Manager.
3. **Proposed Classification** - Specify the proposed classification of this product.
4. **Product Name** - Enter the complete product name of this pesticide as it will appear on the label. The name must be specific to this product only. Duplication of names is not permitted among products of the same company. Do not include any brand name or company line designations.
5. **Name and Address of Applicant** - The name of the firm or person and address shown in your application is the person or firm to whom the registration will be issued. If you are acting in behalf of another party, you must submit authorization from that party to act for them in registration matters. An applicant not residing in the United States must have an authorized agent residing in the United States to act for them in all registration matters. The name and complete mailing address of such an agent must accompany this application.
6. **Expedited Review** - FIFRA section 3 (c) 3 (B) provides for expedited review of applications for registration, or amendments to existing registrations, that are similar or identical to other pesticide products that are currently registered with the EPA. In order for your application to be eligible for expedited review, you must provide us with the EPA Registration Number and product name of the product you believe is similar to or identical to your product. The product must be similar or identical in both formulation and labeled uses.

SECTION II - This section must be completed for all applications submitted to amend the registration only of a currently registered product (Amendment), for a resubmission in response to an Agency letter, for notifications to the Agency, for the submission of final printed labeling, for reregistration and for any other action that pertains to a specific EPA-registered product. This section is not to be used for a new application for registration.

1. **Subject of submission** - Check the applicable block and provide the Agency letter date if appropriate. Provide a brief explanation of the purpose(s) for the submission, such as "the addition of a site, pest or crop (specify)"; "amend the Confidential Statement of Formula by..."; "reregistration submission"; "general label revision of use directions." Attach a separate page if additional space is needed.

SECTION III (Packaging and Container Information) - This Section must be completed for all applications submitted in connection with new registration or applicable amendments.

1. **Type of Packaging** - Check the appropriate block if your product will be packaged in the indicated packaging types. Indicate the size of the individual packets and number per retail container.
2. **Type of Retail Container** - Indicate type of container in which product will be marketed.
3. **Location of Net Contents** - Indicate the location of the net contents information for your product.
4. **Size(s) of Retail Container** - Specify the net contents of all retail containers for your product.
5. **Location of Use Directions** - Indicate the location of the use directions for your product.
6. **Manner in which label is affixed to product** - Indicated the method product label is attached to retail container.

SECTION IV (Contact Point) - This Section must be completed for all applications for Registration actions, i.e., new products registration, resubmission, "me-too," reregistration, etc.

1-5. Self-explanatory.
6. EPA Use Only.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

APR 15 1999

Dr. Stephen J. Wratten
Monsanto Company
600 13th Street, NW, Suite 660
Washington, DC 20005

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

Dear Dr. Wratten:

Subject: Shackle C Herbicide (Update Various Labeling Statements)
EPA Registration No. 524-339
Your Application Dated January 22, 1999

The labeling referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended is acceptable. Please submit three (3) copies of your final printed labeling before you release the product for shipment. A stamped copy of labeling is enclosed for your records.

Please note for future submissions include clean copies of labeling for stamping and for placement on CD Rom.

Sincerely,

Vicki K Walters for

James A. Tompkins
Product Manager 25
Herbicide Branch
Registration Division (7505C)

ACCEPTED

APR 15 1999

Under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, for the pesticide registered under EPA Reg. No 524-339

CONCENTRATE

SHACKLE® C

Herbicide by ~~Monsanto~~

PRECAUTIONARY STATEMENTS

Hazards to Humans and Domestic Animals

Keep out of reach of children.

DANGER!

CAUSES IRREVERSIBLE EYE DAMAGE.
HARMFUL IF SWALLOWED OR INHALED.
MAY CAUSE SKIN IRRITATION.
Do not get in eyes, on skin or on clothing.
Wear goggles or face shield.
Avoid breathing vapor or spray mist.
Wash thoroughly with soap and water after handling.
Remove contaminated clothing and wash before reuse.

FIRST AID: IF IN EYES, immediately flush with plenty of water for at least 15 minutes. Get medical attention.

If ON SKIN, immediately flush with plenty of water. Remove contaminated clothing. Wash clothing before reuse.

IF SWALLOWED, this product will cause gastrointestinal tract irritation. Immediately dilute by swallowing water or milk. Get medical attention.

NOTE TO PHYSICIAN: Probable mucosal damage may contraindicate the use of gastric lavage.

IF INHALED, remove individual to fresh air. Get medical attention if breathing difficulty develops.

In case of an emergency involving this product,
Call Collect, day or night, (314) 694-4000.

Environmental Hazards

~~Do not apply directly to water, to areas where surface water is present or to intertidal areas below the mean high water mark. Do not contaminate water when disposing of equipment washwaters.~~

Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans or other public waters unless in accordance with the requirements of a National Pollutant Discharge Elimination Systems (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage tretment plant authority. For guidance contact your State Water Board or Regional Office of the EPA.

Physical or Chemical Hazards

Solutions of this product should be mixed and stored using only ~~in~~ stainless steel, aluminum, fiberglass, plastic and plastic-lined steel containers.

DO NOT MIX, OR STORE ~~OR APPLY~~ THIS PRODUCT OR ~~SPRAY~~ SOLUTIONS OF THIS PRODUCT IN GALVANIZED ~~STEEL~~ OR UNLINED STEEL (EXCEPT STAINLESS STEEL) CONTAINERS, ~~OR SPRAY TANKS.~~ This product or ~~spray~~ solutions of this product react with such containers and tanks to produce hydrogen gas which may form a highly combustible gas mixture. This gas ~~mixture~~ could flash or explode, causing serious personal injury, if ignited by open flame, spark, welder's torch, lighted cigarette or other ignition source.

DIRECTIONS FOR USE

Read the entire label before using this product.

It is a violation of Federal law to use this product in any manner inconsistent with its labeling.

~~For formulation of products (not to exceed 10% active ingredient) for weed and grass control in industrial, residential and ornamental areas.~~

This product may only be reformulated or repackaged into a herbicide (not to exceed 10% active ingredient) for use in industrial, turf, and ornamental sites; residential sites; or some or all of the following cropping systems: vegetables, citrus, pome fruits, stone fruits, small fruits and berries, tree nuts, cereal grains, animal grasses and forages, tropical fruits, asparagus, avocado, banana, cotton, cranberry, fig, grapes, kiwi, mango, okra, papaya, peanut, persimmon, pineapple, sugarcane and watercress.

Storage and Disposal

Do not contaminate water, foodstuffs, feed or seed by storage or disposal.

DISPOSAL: Wastes of this ~~pesticide~~ product may cause irreversible eye damage and may be dangerous. Improper disposal of excess pesticide, ~~spray mixture,~~ or rinsate is a violation of Federal law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance.

Emptied container retains vapor and product residue. Observe all labeled safeguards until container is cleaned, reconditioned, or destroyed.

~~Triple rinse emptied bulk containers. Then offer for recycling or reconditioning, or dispose of in a manner approved by state and local authorities.~~

Do not reuse container. Triple rinse container. Then puncture and dispose of in a sanitary landfill, or by incineration, or, if allowed by state and local authorities, by burning. If burned, stay out of smoke.

FOR HERBICIDE FORMULATION ONLY

ACTIVE INGREDIENT:	
*Glyphosate, N-(phosphonomethyl)glycine, in the form of its isopropylamine salt ~~of glyphosate~~	41.0%
~~INERT~~ OTHER INGREDIENTS:	59.0%
	100.0%

*Contains 480 grams per litre or 4 pounds per U.S. Gallon of the active ingredient glyphosate, in the form of its isopropylamine salt, ~~of N-(phosphonomethyl)glycine~~ Equivalent to 356 grams per litre or 3 pounds per U.S. gallon of the acid, glyphosate.

This product is protected by U.S. Patent No. 4,405,531. Other patents pending. No license granted under any non-U.S. patent(s).

LIMIT OF WARRANTY AND LIABILITY

Monsanto Company does not warrant any product reformulated or repackaged from this product except in accordance with this Company's stewardship requirements and with express written permission from Monsanto Company.

®Shackle is a registered trademark of Monsanto Company.

EPA Reg. No. 524-339

LOT NO. PACKER NET U.S. GAL.

EPA Est. 239-IA-3

MONSANTO COMPANY, ~~AGRICULTURAL PRODUCTS~~, ST. LOUIS, MISSOURI 63167, U.S.A.

SUBM SS ON REV BY RECORD	G	132401		133			DATE RECEIVED	MO	DAY	YR	
3. IS A FEE REQUIRED? ☐ YES ☐ NO		4. PETITION NO.						01	25	99	
5. METHOD OF SUPPORT ☐ SA ☐ SB ☐ SC		7. PRODUCT MANAGER					5. RECEIVED BY TEAM	MO	DAY	YR	
9. DATE FILLED	10. DATE PUBLISHED	11. ACTION TYPE	Stacking C - Update 300 series label statements				NO.	6. PROJECTED RETURN			
4/23/99								MO	DAY	YR	
							CODE	12. OUTGOING DATE			
								MO	DAY	YR	

REVIEW SEQ NO	REVIEW TYPE CODE	REVIEW TYPE	REVIEWER CODE (Initials)	SIGNATURE OF REVIEWER	COMMENT CODE	DATE REVIEW COMPLETED MO	DAY	YR
	A	REVIEWABILITY TEAM						
	B	PRODUCT MANAGER TEAM EFFICACY REVIEW						
	C	PRODUCT MANAGER TEAM HUMAN SAFETY REVIEW						
	D	PRODUCT MANAGER TEAM ENVIRONMENTAL SAFETY REVIEW						
	E	PRODUCT MANAGER TEAM RECLASSIFICATION REVIEW						
	F	PRODUCT MANAGER		UKW	NAC	04	13	99
	G	INTERAGENCY REFERRAL						
	H	COST-BENEFIT REVIEW						
	I	PUBLIC COMMENTS REVIEW						
	J	EEB BRANCH INSECTICIDE EFFICACY						
	K	EEB BRANCH HERBICIDE EFFICACY						
	L	EEB BRANCH FUNGICIDE EFFICACY						
	M	EEB BRANCH ANTIMICROBIAL EFFICACY						
	N	EEB BRANCH DISINFECTANT EFFICACY						
	O	CHEMISTRY BRANCH RESIDUE CHEMISTRY						
	P	EEB BRANCH ENVIRONMENTAL CHEMISTRY						
	Q	TOXICOLOGY BRANCH HUMAN SAFETY						
	R	EEB BRANCH ENVIRONMENTAL SAFETY						
	S							
	T							

PRODUCT MANAGER SIGNATURE	TYPE OF RESPONSE	CODE

EPA Form 8570-13 (5-75)

A B

Please read instructions on reverse before completing form.

Form Approved. OMB No. 2070-0060. Approval expires 05-31-98

EPA

United States
Environmental Protection Agency
Washington, DC 20460

☐ Registration
☒ Amendment
☐ Other

OPP Identifier Number: 250895

Application for Pesticide - Section I

1. Company/Product Number: 524-339

2. EPA Product Manager: Mr. James Tompkins

3. Proposed Classification: ☒ None ☐ Restricted

4. Company/Product (Name): Shackle C Herbicide

PM#: 25

5. Name and Address of Applicant *(Include ZIP Code)*
Monsanto Company
600 13th Street, N.W., Suite 660
Washington, DC 20005

☐ *Check if this is a new address*

6. **Expedited Review.** In accordance with FIFRA Section 3(c)(3)(b)(i), my product is similar or identical in composition and labeling to:
EPA Reg. No. _____
Product Name _____

Section - II

☒ Amendment - Explain below.
☐ Resubmission in response to Agency letter dated _____
☐ Notification - Explain below.
☐ Final printed labels in response to Agency letter dated _____
☐ "Me Too" Application.
☐ Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

Update various labeling statements

Section - III

1. Material This Product Will Be Packaged In:

Child-Resistant Packaging	Unit Packaging	Water Soluble Packaging	2. Type of Container
☐ Yes* ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Metal ☐ Plastic ☐ Glass ☐ Paper ☐ Other (Specify)
* *Certification must be submitted*	If "Yes" Unit Packaging wgt. / No. per container	If "Yes" Package wgt / No. per container	

3. Location of Net Contents Information: ☐ Label ☐ Container

4. Size(s) Retail Container

5. Location of Label Directions: ☐ On Label ☐ On Labeling accompanying product

6. Manner in Which Label is Affixed to Product: ☐ Lithograph ☐ Paper glued ☐ Stenciled ☐ Other _____

Section - IV

1. Contact Point *(Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)*

Name	Title	Telephone No. (Include Area Code)
Russell Schneider, PH.D.	Agricultural Regulation Director	(202) 783-2460

Certification

I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

2. Signature	3. Title	6. Date Application Received (Stamped)
Stephen J. Wratten	Manager, Registrations	
4. Typed Name: Stephen J. Wratten, Ph.D.	5. Date: January 22, 1999	

EPA Form 8570-1 (Rev. 6-94) Previous editions are obsolete. White - EPA File Copy (original) Yellow - Applicant Copy

PAPERWORK REDUCTION ACT NOTICE and INSTRUCTIONS

PAPERWORK REDUCTION ACT NOTICE: Public reporting burden for this collection of information is estimated to average 0.85 hour per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to Chief, Information Policy Branch, (2136), U.S. Environmental Protection Agency, 401 M Street, SW, Washington, DC 20460.

INSTRUCTIONS: This form is to be used for all applications for new registration, end use reregistration, amendment, resubmission, to applications for notifications, final printed labeling, reregistration, etc. In order to process an application for a new registration submitted on this form, the following material must accompany the application:

1. Certification with Respect to Citation of Data (EPA Form 8570-29). [If not exempted by 40 CFR 152.81 (b) (4)];
2. Confidential Statement of Formula (EPA Form 8570-4);
3. Formulator's Exemption Statement (EPA Form 8570-27);
4. Five copies of draft labeling;
5. Three copies of any data submitted;
6. Authorization letter where applicable;
7. Matrices where applicable.

Submission of Labeling - Labeling should first be submitted in the form of draft labels with all applications for new registration. Such draft labels may be in the form of typed label text on 8.5 x 11 inch paper for submission or a mockup of the proposed label. If prepared for mockup, it should be constructed in a way as to facilitate storage in an 8.5 x 11 inch file. Mockup labels significantly smaller than 8.5 x 11 inches should be mounted on x 11 inch paper for submission.

Submission of Data - Data submitted in support of this application must be submitted in accordance with PR Notice 86-5.

SPECIFIC INSTRUCTIONS: Please read the instructions listed below before completing this application. First determine the type of registration action, listed in Block A, for which you are submitting this application. For applications submitted in connection with New Registration actions, Sections I, III, and IV must be completed by the applicant. For applications submitted in connection with amended reregistration actions, resubmissions, notifications, reregistrations, etc., Sections I, II, and IV must be completed by the applicant.

Block A - Check the appropriate action for which you are submitting this form.

SECTION I - This section must be completed, as applicable, for all registration actions.

1. **Company/Product Number** - Insert your Company Number, if one has been assigned by EPA. This number may have been assigned to you as a basic registrant, a distributor, or as an establishment. If your product is registered, insert the Product Number.
2. **EPA Product Manager** - If known, fill in the name and PM number of the EPA Product Manager.
3. **Proposed Classification** - Specify the proposed classification of this product.
4. **Product Name** - Enter the complete product name of this pesticide as it will appear on the label. The name must be specific to this product only. Duplication of names is not permitted among products of the same company. Do not include any brand name or company line designations.
5. **Name and Address of Applicant** - The name of the firm or person and address shown in your application is the person or firm to whom the registration will be issued. If you are acting in behalf of another party, you must submit authorization from that party to act for them in registration matters. An applicant not residing in the United States must have an authorized agent residing in the United States to act for them in all registration matters. The name and complete mailing address of such an agent must accompany this application.
6. **Expedited Review** - FIFRA section 3 (c) 3 (B) provides for expedited review of applications for registration, or amendments to existing registrations, that are similar or identical to other pesticide products that are currently registered with the EPA. In order for your application to be eligible for expedited review, you must provide us with the EPA Registration Number and product name of the product you believe is similar to or identical to your product. The product must be similar or identical in both formulation and labeled uses.

SECTION II - This section must be completed for all applications submitted to amend the registration only of a currently registered product (Amendment), for a resubmission in response to an Agency letter, for notifications to the Agency, for the submission of final printed labeling, for reregistration and for any other action that pertains to a specific EPA-registered product. This section is not to be used for a new application for registration.

1. **Subject of submission** - Check the applicable block and provide the Agency letter date if appropriate. Provide a brief explanation of the purpose(s) for the submission, such as "the addition of a site, pest or crop (specify)"; "amend the Confidential Statement of Formula by..."; "reregistration submission"; "general label revision of use directions." Attach a separate page if additional space is needed.

SECTION III (Packaging and Container Information) - This Section must be completed for all applications submitted in connection with new registration or applicable amendments.

1. **Type of Packaging** - Check the appropriate block if your product will be packaged in the indicated packaging types. Indicate the size of the individual packets and number per retail container.
2. **Type of Retail Container** - Indicate type of container in which product will be marketed.
3. **Location of Net Contents** - Indicate the location of the net contents information for your product.
4. **Size(s) of Retail Container** - Specify the net contents of all retail containers for your product.
5. **Location of Use Directions** - Indicate the location of the use directions for your product.
6. **Manner in which label is affixed to product** - Indicated the method product label is attached to retail container.

SECTION IV (Contact Point) - This Section must be completed for all applications for Registration actions, i.e., new products registration, resubmission, "me too," reregistration, etc.

1-5. Self-explanatory.
6. EPA Use Only.

B

MONSANTO
Food · Health · Hope™

MONSANTO COMPANY
600 13TH STREET, N.W.
SUITE 660
WASHINGTON, D.C. 20005
TEL: (202) 783-2460
FAX: (202) 783-2468

January 22, 1999

Hand Delivered

Office of Pesticide Programs
Document Processing Center (AMEND)
U. S. Environmental Protection Agency
Room 266A, Crystal Mall #2
1921 Jefferson Davis Highway
Arlington, VA 22202

Attention: Mr. James A. Tompkins (7505C)
Team Leader (25)

Subject: Shackle C Herbicide (EPA Reg. No. 524-339)
Update Various Labeling Statements

Dear Mr. Tompkins:

Shackle C Herbicide is a manufacturing use product (MUP) which can be used by formulators to prepare glyphosate herbicides. The present label text was approved by the Agency on 20-Oct-1997 in conjunction with its reregistration. In the autumn of 1998, Monsanto and EPA engaged in discussions pertaining to reformulation limitations on the Shackle C Herbicide label. A label amendment dated 11-Aug-1998 was rejected on that basis. We believe we have now agreed on acceptable wording. At this time, Monsanto proposes new draft label text in five (5) copies for Agency review and approval to make the following changes:

- In EPA's label manual, registrants of MUP are directed to include a statement specifying the use sites for which end use products can be prepared using the MUP. Monsanto now proposes to utilize a modified version of the statement that is presently approved for MON 0139 62% Technical Solution (524-333) on all it's glyphosate MUPs.

- All Monsanto glyphosate labels are intended to identify the active ingredient by the term "glyphosate" and by it's chemical name. The proposed change will make this ingredient statement consistent with other labels.
- The company name "by Monsanto" is removed from the position immediately below the brand name. Company identity is still provided at the lower right.
- Under Environmental Hazards, the statement pertaining to applications is deleted, since this product is not labeled for application, and the NPDES statement is substituted, as specified in the Glyphosate RED for manufacturing-use products. Other spurious references to spraying or spray mixtures are deleted throughout the label.
- Other minor wording changes intended to achieve consistency with other labels, including the substitution of the word "other" for the word "inert" in the Ingredients Statement (PR Notice 97-6), are also proposed.
- The Limit of Warranty and Liability statement has been added to reflect Monsanto's interests in limiting responsibility for products other formulators may produce from this product without Monsanto's agreement. No other references to reformulation or repackaging limitations are made.

If you have any questions on this matter please feel free to contact me through Dr. Russell P. Schneider or directly at 314-694-1582.

Sincerely,

Stephen J. Wratten
Manager, Registrations

cc: R. P. Schneider
D. Fee-White

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

APR 15 1999

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

Dr. Stephen J. Wratten
Monsanto Company
600 13th Street, NW, Suite 660
Washington, DC 20005

Dear Dr. Wratten:

Subject: Exchange Herbicide (Update Various Labeling Statements)
EPA Registration No. 524-339
Your Application Dated January 22, 1999

The labeling referred to above, submitted in connection with connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended is acceptable. Please submit three(3) copies of your final printed labeling before you release the product for shipment. A stamped copy of labeling is enclosed for your records.

Please note for future submissions include clean labels for stamped and for placement on CD rom.

Sincerely,

Vickie K Walters for
James A. Tompkins
Product Manager 25
Herbicide Branch
Registration Division (7505C)

ACCEPTED
APR 15 1999

Under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, for the pesticide registered under EPA Reg. No 524-339

EXCHANGE®

HERBICIDE ~~BY~~ ~~Monsanto~~

~~Read "LIMIT OF WARRANTY AND LIABILITY" before buying or using. If terms are not acceptable, return at once unopened.~~

~~REFORMULATION OR REPACKAGING IS PROHIBITED; EXCEPT IN ACCORDANCE WITH AN EXPRESS WRITTEN AGREEMENT WITH MONSANTO COMPANY.~~

PRECAUTIONARY STATEMENTS

Hazards to Humans and Domestic Animals

Keep out of reach of children.

DANGER!

CAUSES IRREVERSIBLE EYE DAMAGE.
HARMFUL IF SWALLOWED OR INHALED.
MAY CAUSE SKIN IRRITATION.

Do not get in eyes, on skin or on clothing.
Wear goggles or face shield.
Avoid breathing vapor or spray mist.
Wash thoroughly with soap and water after handling.
Remove contaminated clothing and wash before reuse.

FIRST AID: IF IN EYES, immediately flush with plenty of water for at least 15 minutes. Get medical attention.

If ON SKIN, immediately flush with plenty of water. Remove contaminated clothing. Wash clothing before reuse.

IF SWALLOWED, this product will cause gastrointestinal tract irritation. Immediately dilute by swallowing water or milk. Get medical attention.

NOTE TO PHYSICIAN: Probable mucosal damage may contraindicate the use of gastric lavage.

IF INHALED, remove individual to fresh air. Get medical attention if breathing difficulty develops.

In case of an emergency involving this product,
Call Collect, day or night, (314) 694-4000.

Environmental Hazards

~~Do not apply directly to water, to areas where surface water is present or to intertidal areas below the mean high water mark. Do not contaminate water when disposing of equipment washwaters.~~

Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans or other waters unless in accordance with the requirements of a National Pollutant Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA.

Physical or Chemical Hazards

Solutions of this product should be mixed and stored using only stainless steel, aluminum, fiberglass, plastic or plastic-lined steel containers.

DO NOT MIX OR STORE THIS PRODUCT OR SOLUTIONS OF THIS PRODUCT IN GALVANIZED ~~STEEL~~ OR UNLINED STEEL (EXCEPT STAINLESS STEEL) CONTAINERS. ~~OR SPRAY TANKS~~. This product or solutions of this product react with such containers and tanks to produce hydrogen gas which may form a highly combustible gas mixture. This gas ~~mixture~~ could flash or explode, causing serious personal injury, if ignited by open flame, spark, welder's torch, lighted cigarette or other ignition source.

DIRECTIONS FOR USE

Read the entire label before using this product.

It is a violation of Federal law to use this product in any manner inconsistent with its labeling.

This product may only be reformulated or repackaged into a herbicide for use in industrial, turf, and ornamental sites; residential sites; or some or all of the following cropping systems: vegetables, citrus, pome fruits, stone fruits, small fruits and berries, tree nuts, cereal grains, animal grasses and forages, tropical fruits, asparagus, avocado, banana, cotton, cranberry, fig, grapes, kiwi, mango, okra, papaya, peanut, persimmon, pineapple, sugarcane and watercress.

Storage and Disposal

Do not contaminate water, foodstuffs, feed or seed by storage or disposal.

DISPOSAL: Wastes of this ~~pesticide~~ product may cause irreversible eye damage and may be dangerous. Improper disposal of excess pesticide, ~~spray mixture,~~ or rinsate is a violation of Federal law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance.

Emptied container retains vapor and product residue. Observe all labeled safeguards until container is ~~cleaned, reconditioned, or~~ destroyed. ~~DO NOT CUT OR WELD ON OR NEAR THIS CONTAINER.~~

Do not reuse container. Triple rinse container. Then puncture and dispose of in a sanitary landfill, or by incineration, or, if allowed by state and local authorities, by burning. If burned, stay out of smoke.

~~FOR MANUFACTURING, REFORMULATION AND REPACKAGING AS A HERBICIDE ONLY.~~

ACTIVE INGREDIENT:	
*Glyphosate, N-(phosphonomethyl)glycine, in the form of its isopropylamine salt	41.0%
~~INERT~~ OTHER INGREDIENTS:	59.0%
	100.0%

*Contains 480 grams per litre or 4 pounds per U.S. Gallon of the active ingredient glyphosate, in the form of its isopropylamine salt. Equivalent to 356 grams per litre or 3 pounds per U.S. gallon of the acid, glyphosate.

This product is protected by U.S. Patent No. 4,405,531. Other patents pending. No license granted under any non-U.S. patent(s).

~~LIMIT OF WARRANTY AND LIABILITY~~

~~This Company warrants that this product conforms to the chemical description on this label. NO OTHER EXPRESS WARRANTY OR IMPLIED WARRANTY OF FITNESS FOR PARTICULAR PURPOSE OR MERCHANTABILITY IS MADE. This warranty is also subject to the conditions and limitations stated herein.~~

~~Buyer and all users shall promptly notify this Company of any claims whether based in contract, negligence, strict liability, other tort or otherwise.~~

~~Buyer and all users are responsible for all loss or damage from use or handling which results from conditions beyond the control of this Company, including, but not limited to, uses or applications in any manner not explicitly set forth in this label or application to or contact with desirable vegetation.~~

~~THE EXCLUSIVE REMEDY OF THE USER OR BUYER AND THE LIMIT OF THE LIABILITY OF THIS COMPANY OR ANY OTHER SELLER FOR ANY AND ALL LOSSES, INJURIES OR DAMAGES RESULTING FROM THE USE OR HANDLING OF THIS PRODUCT (INCLUDING CLAIMS BASED IN CONTRACT, NEGLIGENCE, STRICT LIABILITY, OTHER TORT OR OTHERWISE) SHALL BE THE PURCHASE PRICE PAID BY THE USER OR BUYER FOR THE QUANTITY OF THIS PRODUCT INVOLVED , OR AT THE ELECTION OF THIS COMPANY OR ANY OTHER SELLER, THE REPLACEMENT OF SUCH QUANTITY, OR, IF NOT ACQUIRED BY PURCHASE, REPLACEMENT OF SUCH QUANTITY. IN NO EVENT SHALL THIS COMPANY OR ANY OTHER SELLER BE LIABLE FOR ANY INCIDENTAL, CONSEQUENTIAL OR SPECIAL DAMAGES.~~

~~Buyer and all users are deemed to have accepted the terms of this LIMIT OF WARRANTY AND LIABILITY which may not be varied by any verbal or written agreement.~~

LIMIT OF WARRANTY AND LIABILITY

Monsanto Company does not warrant any product reformulated or repackaged from this product except in accordance with this Company's stewardship requirements and with express written permission from Monsanto Company.

Exchange is a ® registered trademark of Monsanto Company.

~~MONSANTO COMPANY~~
ST. LOUIS, MISSOURI 63167 U.S.A.

EPA Reg. No. 524-339

EPA Est. 524-LA-1

21006W2-2/53L

NET 54 U.S. GAL.

(01) 0 00 70183 50409 1

SUBMISSION RECEIVED RECORD	G	152401	13/91	10	12599

3. IS A PUBLIC DATA SUMMARY NECESSARY? ☐ YES ☐ NO	4. PETITION NO.	5. RECEIVED ON YEAR: MO. DAY YR.
6. METHOD OF SUPPORT ☐ SA ☐ SB ☐ SC	7. PRODUCT MANAGER	NO. 8. PROJECTED RETURN: MO. DAY YR.
9. DATE PULLED: 4/13/99	10. DATE PUBLISHED	11. ACTION TYPE: Exchange Herbicide - Update various labeling statements	CODE 12. OUTGOING DATE: MO. DAY YR.

NEW SCR	REVIEW TYPE CODE	REVIEW TYPE	REVIEWER CODE (Initials)	SIGNATURE OF REVIEWER	COMMENT CODE	DATE REVIEW COMPLETED: MO. DAY YR.
	A	REVIEWABILITY TEAM				
	B	PRODUCT MANAGER TEAM EFFICACY REVIEW				
	C	PRODUCT MANAGER TEAM HUMAN SAFETY REVIEW				
	D	PRODUCT MANAGER TEAM ENVIRONMENTAL SAFETY REVIEW				
	E	PRODUCT MANAGER TEAM RECONSIDERATION REVIEW				
	F	PRODUCT MANAGER		300 UKW	WAC	04 13 99
	G	INTERAGENCY REFERRAL				
	H	COST-BENEFIT REVIEW				
	I	PUBLIC COMMENTS REVIEW				
	J	EEB BRANCH INSECTICIDE EFFICACY				
	K	EEB BRANCH HERBICIDE EFFICACY				
	L	EEB BRANCH FUNGICIDE EFFICACY				
	M	EEB BRANCH ANTIMICROBIAL EFFICACY				
	N	EEB BRANCH DISINFECTANT EFFICACY				
	O	CHEMISTRY BRANCH RESIDUE CHEMISTRY				
	P	EEB BRANCH ENVIRON. + MENTAL CHEMISTRY				
	Q	TOXICOLOGY BRANCH HUMAN SAFETY				
	R	EEB BRANCH ENVIRON. MENTAL SAFETY				
	S					
	T					

PRODUCT MANAGER SIGNATURE	TYPE OF RESPONSE	CODE

EPA Form 8570-1 8 (5-76)

Please read instructions on reverse before completing form.

Form Approved. OMB No. 2070-0060. Approval expires 05-31-98

EPA

United States
Environmental Protection Agency
Washington, DC 20460

☐ Registration
☒ Amendment
☐ Other

OPP Identifier Number: 250898

Application for Pesticide - Section I

1. Company/Product Number: 524-339

2. EPA Product Manager: Mr. James Tompkins

3. Proposed Classification: ☒ None ☐ Restricted

4. Company/Product (Name): Exchange Herbicide

PM#: 25

5. Name and Address of Applicant *(Include ZIP Code)*
Monsanto Company
600 13th Street, N.W., Suite 660
Washington, DC 20005

☐ *Check if this is a new address*

6. **Expedited Review.** In accordance with FIFRA Section 3(c)(3)(b)(i), my product is similar or identical in composition and labeling to:
EPA Reg. No. _____
Product Name _____

Section - II

☒ Amendment - Explain below.
☐ Resubmission in response to Agency letter dated _____
☐ Notification - Explain below.
☐ Final printed labels in response to Agency letter dated _____
☐ "Me Too" Application.
☐ Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

Update various labeling statements

Section - III

1. Material This Product Will Be Packaged In:

Child-Resistant Packaging: ☐ Yes* ☐ No
** Certification must be submitted*

Unit Packaging: ☐ Yes ☐ No
If "Yes" Unit Packaging wgt. / No. per container

Water Soluble Packaging: ☐ Yes ☐ No
If "Yes" Package wgt / No. per container

2. Type of Container: ☐ Metal ☐ Plastic ☐ Glass ☐ Paper ☐ Other (Specify) _____

3. Location of Net Contents Information: ☐ Label ☐ Container

4. Size(s) Retail Container

5. Location of Label Directions: ☐ On Label ☐ On Labeling accompanying product

6. Manner in Which Label is Affixed to Product: ☐ Lithograph ☐ Paper glued ☐ Stenciled ☐ Other _____

Section - IV

1. Contact Point *(Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)*

Name: Russell P. Schneider, Ph.D.
Title: Agricultural Regulation Director
Telephone No. (Include Area Code): (202) 783-2460

Certification

I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

2. Signature: Stephen J. Wratten

3. Title: Manager, Registrations

4. Typed Name: Stephen J. Wratten, Ph.D.

5. Date: January 22, 1999

6. Date Application Received (Stamped)

EPA Form 8570-1 (Rev. 8-94) Previous editions are obsolete. White - EPA File Copy (original) Yellow - Applicant Copy

PAPERWORK REDUCTION ACT NOTICE and INSTRUCTIONS

PAPERWORK REDUCTION ACT NOTICE: Public reporting burden for this collection of information is estimated to average 0.85 hour per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to Chief, Information Policy Branch, (2136), U.S. Environmental Protection Agency, 401 M Street, SW, Washington, DC 20460.

INSTRUCTIONS: This form is to be used for all applications for new registration, end use reregistration, amendment, resubmission, to applications for notifications, final printed labeling, reregistration, etc. In order to process an application for a new registration submitted on this form, the following material must accompany the application:

1. Certification with Respect to Citation of Data (EPA Form 8570-29). [If not exempted by 40 CFR 152.81 (b) (4)];
2. Confidential Statement of Formula (EPA Form 8570-4);
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4. Five copies of draft labeling;
5. Three copies of any data submitted;
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Submission of Labeling - Labeling should first be submitted in the form of draft labels with all applications for new registration. Such draft labels may be in the form of typed label text on 8.5 x 11 inch paper for submission or a mockup of the proposed label. If prepared for mockup, it should be constructed in a way as to facilitate storage in an 8.5 x 11 inch file. Mockup labels significantly smaller than 8.5 x 11 inches should be mounted on x 11 inch paper for submission.

Submission of Data - Data submitted in support of this application must be submitted in accordance with PR Notice 86-5.

SPECIFIC INSTRUCTIONS: Please read the instructions listed below before completing this application. First determine the type of registration action, listed in Block A, for which you are submitting this application. For applications submitted in connection with New Registration actions, Sections I, III, and IV must be completed by the applicant. For applications submitted in connection with amended reregistration actions, resubmissions, notifications, reregistrations, etc., Sections I, II, and IV must be completed by the applicant.

Block A - Check the appropriate action for which you are submitting this form.

SECTION I - This section must be completed, as applicable, for all registration actions.

1. Company/Product Number - Insert your Company Number, if one has been assigned by EPA. This number may have been assigned to you as a basic registrant, a distributor, or as an establishment. If your product is registered, insert the Product Number.
2. EPA Product Manager - If known, fill in the name and PM number of the EPA Product Manager.
3. Proposed Classification - Specify the proposed classification of this product.
4. Product Name - Enter the complete product name of this pesticide as it will appear on the label. The name must be specific to this product only. Duplication of names is not permitted among products of the same company. Do not include any brand name or company line designations.
5. Name and Address of Applicant - The name of the firm or person and address shown in your application is the person or firm to whom the registration will be issued. If you are acting in behalf of another party, you must submit authorization from that party to act for them in registration matters. An applicant not residing in the United States must have an authorized agent residing in the United States to act for them in all registration matters. The name and complete mailing address of such an agent must accompany this application.
6. Expedited Review - FIFRA section 3 (c) 3 (B) provides for expedited review of applications for registration, or amendments to existing registrations, that are similar or identical to other pesticide products that are currently registered with the EPA. In order for your application to be eligible for expedited review, you must provide us with the EPA Registration Number and product name of the product you believe is similar to or identical to your product. The product must be similar or identical in both formulation and labeled uses.

SECTION II - This section must be completed for all applications submitted to amend the registration only of a currently registered product (Amendment), for a resubmission in response to an Agency letter, for notifications to the Agency, for the submission of final printed labeling, for reregistration and for any other action that pertains to a specific EPA-registered product. This section is not to be used for a new application for registration.

1. Subject of submission - Check the applicable block and provide the Agency letter date if appropriate. Provide a brief explanation of the purpose(s) for the submission, such as "the addition of a site, pest or crop (specify)"; "amend the Confidential Statement of Formula by..."; "reregistration submission"; "general label revision of use directions." Attach a separate page if additional space is needed.

SECTION III (Packaging and Container Information) - This Section must be completed for all applications submitted in connection with new registration or applicable amendments.

1. Type of Packaging - Check the appropriate block if your product will be packaged in the indicated packaging types. Indicate the size of the individual packets and number per retail container.
2. Type of Retail Container - Indicate type of container in which product will be marketed.
3. Location of Net Contents - Indicate the location of the net contents information for your product.
4. Size(s) of Retail Container - Specify the net contents of all retail containers for your product.
5. Location of Use Directions - Indicate the location of the use directions for your product.
6. Manner in which label is affixed to product - Indicated the method product label is attached to retail container.

SECTION IV (Contact Point) - This Section must be completed for all applications for Registration actions, i.e., new products registration, resubmission, "me-too," reregistration, etc.

1-5. Self-explanatory.
6. EPA Use Only.

MONSANTO

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MONSANTO COMPANY
600 13TH STREET, N.W.
SUITE 660
WASHINGTON, D.C. 20005
TEL: (202) 783-2460
FAX: (202) 783-2468

January 22, 1999

Hand Delivered

Office of Pesticide Programs
Document Processing Center (AMEND)
U. S. Environmental Protection Agency
Room 266A, Crystal Mall #2
1921 Jefferson Davis Highway
Arlington, VA 22202

Attention: Mr. James A. Tompkins (7505C)
Team Leader (25)

Subject: Exchange Herbicide (EPA Reg. No. 524-339)
Update Various Labeling Statements

Dear Mr. Tompkins:

Exchange Herbicide is a manufacturing use product (MUP) which can be used by formulators to prepare glyphosate herbicides. The present label text was approved by the Agency on 20-Oct-1997 in conjunction with its reregistration. In the autumn of 1998, Monsanto and EPA engaged in discussions pertaining to reformulation limitations on the Exchange Herbicide label. A label amendment dated 11-Aug-1998 was rejected on that basis. We believe we have now agreed on acceptable wording. At this time, Monsanto proposes new draft label text in five (5) copies for Agency review and approval to make the following changes:

- In EPA's label manual, registrants of MUP are directed to include a statement specifying the use sites for which end use products can be prepared using the MUP. Monsanto now proposes to utilize a modified version of the statement that is presently approved for MON 0139 62% Technical Solution (524-333) on all it's glyphosate MUPs. The existing statements specifying directions for reformulation into herbicides is now redundant and is to be deleted.
- The Limit of Warranty and Liability statement has been modified to reflect Monsanto's interests in limiting responsibility for products other formulators may produce from

this product without Monsanto's agreement. The remainder of existing text is no longer needed. Other reformulation and repackaging limitation statements are deleted.

- The company name "by Monsanto" is removed from the position immediately below the brand name. Company identity is still provided at the lower right.
- Under Environmental Hazards, the statement pertaining to applications is deleted, since this product is not labeled for application, and the NPDES statement is substituted, as specified in the Glyphosate RED for manufacturing-use products. Other spurious references to spraying or spray mixtures are deleted throughout the label.
- Exchange is now provided in plastic drums which are intended for single use. Certain statements in the storage and disposal section are intended for steel drums, and are now outdated and proposed for deletion.
- Other minor wording changes intended to achieve consistency with other labels, including the substitution of the word "other" for the word "inert" in the Ingredients Statement (PR Notice 97-6), are also proposed.

If you have any questions on this matter please feel free to contact me through Dr. Russell P. Schneider or directly at 314-694-1582.

Sincerely,

Stephen J. Wratten
Manager, Registrations

cc: R. P. Schneider
D. Fee-White

36 B 7-3

Please read instructions on reverse before completing form. Form Approved. OMB No. 2070-0060. Approval expires 05-31-98

EPA

United States
Environmental Protection Agency
Washington, DC 20460

☐ Registration
☐ Amendment
☒ Other

OPP Identifier Number
250852

Application for Pesticide - Section I

1. Company/Product Number	2. EPA Product Manager	3. Proposed Classification
524-339	Mr. James Tompkins	☒ None ☐ Restricted
4. Company/Product (Name)	PM#	
MON 78087 Herbicide ??	25	

5. Name and Address of Applicant *(Include ZIP Code)*

Monsanto Company
600 13th Street, N.W., Suite 660
Washington, DC 20005

☐ *Check if this is a new address*

6. **Expedited Review.** In accordance with FIFRA Section 3(c)(3)(b)(i), my product is similar or identical in composition and labeling to:

NOTIFICATION
NOV 12 1998

EPA Reg. No. _____

Product Name _____

Section - II

☐ Amendment - Explain below.
☐ Resubmission in response to Agency letter dated _____
☒ Notification - Explain below.
☐ Final printed labels in response to Agency letter dated _____
☐ "Me Too" Application.
☐ Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

Notification of a new brand name: MON 78087 Herbicide

Section - III

1. Material This Product Will Be Packaged In:

Child-Resistant Packaging	Unit Packaging		Water Soluble Packaging		2. Type of Container
☐ Yes* ☐ No	☐ Yes ☐ No		☐ Yes ☐ No		☐ Metal ☐ Plastic ☐ Glass ☐ Paper ☐ Other (Specify)
*Certification must be submitted	If "Yes" Unit Packaging wgt.	No. per container	If "Yes" Package wgt	No. per container	

3. Location of Net Contents Information	4. Size(s) Retail Container	5. Location of Label Directions
☐ Label ☐ Container		☐ On Label ☐ On Labeling accompanying product

6. Manner in Which Label is Affixed to Product ☐ Lithograph ☐ Paper glued ☐ Stenciled ☐ Other _____

Section - IV

1. Contact Point *(Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)*

Name	Title	Telephone No. (Include Area Code)
Dr. Russell P. Schneider	Agricultural Regulation Director	(202) 783-2460

Certification

I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

2. Signature	3. Title	6. Date Application Received (Stamped)
Stephen J. Wratten	Manager, Registrations	
4. Typed Name: Stephen J. Wratten, Ph.D.	5. Date: November 4, 1998	

EPA Form 8570-1 (Rev. 8-94) Previous editions are obsolete. White - EPA File Copy (original) Yellow - Applicant Copy

PAPERWORK REDUCTION ACT NOTICE and INSTRUCTIONS

PAPERWORK REDUCTION ACT NOTICE: Public reporting burden for this collection of information is estimated to average 0.85 hour per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to Chief, Information Policy Branch, (2136), U.S. Environmental Protection Agency, 401 M Street, SW, Washington, DC 20460.

INSTRUCTIONS: This form is to be used for all applications for new registration, end use reregistration, amendment, resubmission, to applications for notifications, final printed labeling, reregistration, etc. In order to process an application for a new registration submitted on this form, the following material must accompany the application:

1. Certification with Respect to Citation of Data (EPA Form 8570-29). [If not exempted by 40 CFR 152.81 (b) (4)];
2. Confidential Statement of Formula (EPA Form 8570-4);
3. Formulator's Exemption Statement (EPA Form 8570-27);
4. Five copies of draft labeling;
5. Three copies of any data submitted;
6. Authorization letter where applicable;
7. Matrices where applicable.

Submission of Labeling - Labeling should first be submitted in the form of draft labels with all applications for new registration. Such draft labels may be in the form of typed label text on 8.5 x 11 inch paper for submission or a mockup of the proposed label. If prepared for mockup, it should be constructed in a way as to facilitate storage in an 8.5 x 11 inch file. Mockup labels significantly smaller than 8.5 x 11 inches should be mounted on 8.5 x 11 inch paper for submission.
Submission of Data - Data submitted in support of this application must be submitted in accordance with PR Notice 86-5.

SPECIFIC INSTRUCTIONS: Please read the instructions listed below before completing this application. First determine the type of registration action, listed in Block A, for which you are submitting this application. For applications submitted in connection with New Registration actions, Sections I, III, and IV must be completed by the applicant. For applications submitted in connection with amended reregistration actions, resubmissions, notifications, reregistrations, etc., Sections I, II, and IV must be completed by the applicant.
Block A - Check the appropriate action for which you are submitting this form.

SECTION I - This section must be completed, as applicable, for all registration actions.

1. **Company/Product Number** - Insert your Company Number, if one has been assigned by EPA. This number may have been assigned to you as a basic registrant, a distributor, or as an establishment. If your product is registered, insert the Product Number.
2. **EPA Product Manager** - If known, fill in the name and PM number of the EPA Product Manager.
3. **Proposed Classification** - Specify the proposed classification of this product.
4. **Product Name** - Enter the complete product name of this pesticide as it will appear on the label. The name must be specific to this product only. Duplication of names is not permitted among products of the same company. Do not include any brand name or company line designations.
5. **Name and Address of Applicant** - The name of the firm or person and address shown in your application is the person or firm to whom the registration will be issued. If you are acting in behalf of another party, you must submit authorization from that party to act for them in registration matters. An applicant not residing in the United States must have an authorized agent residing in the United States to act for them in all registration matters. The name and complete mailing address of such an agent must accompany this application.
6. **Expedited Review** - FIFRA section 3 (c) 3 (B) provides for expedited review of applications for registration, or amendments to existing registration that are similar or identical to other pesticide products that are currently registered with the EPA. In order for your application to be eligible for expedited review, you must provide us with the EPA Registration Number and product name of the product you believe is similar to or identical to your product. The product must be similar or identical in both formulation and labeled uses.

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SECTION III (Packaging and Container Information) - This Section must be completed for all applications submitted in connection with new registration or applicable amendments.

1. **Type of Packaging** - Check the appropriate block if your product will be packaged in the indicated packaging types. Indicate the size of the individual packets and number per retail container.
2. **Type of Retail Container** - Indicate type of container in which product will be marketed.
3. **Location of Net Contents** - Indicate the location of the net contents information for your product.
4. **Size(s) of Retail Container** - Specify the net contents of all retail containers for your product.
5. **Location of Use Directions** - Indicate the location of the use directions for your product.
6. **Manner in which label is affixed to product** - Indicated the method product label is attached to retail container.

SECTION IV (Contact Point) - This Section must be completed for all applications for Registration actions, i.e., new products registration, resubmission, "me-too," reregistration, etc.

1-5. Self-explanatory.
6. EPA Use Only.

NOTIFICATION
NOV 12 1998

MON 78087

Herbicide by Monsanto

Water soluble herbicide for nonselective control of many annual and perennial weeds.
Avoid contact with foliage, green stems, or fruit of crops, desirable plants and trees, since severe injury or destruction may result.

PRECAUTIONARY STATEMENTS

Hazards to Humans and Domestic Animals

Keep out of reach of children.

DANGER! PELIGRO!

Si usted no entiende la etiqueta, busque a alguien para que se la explique a usted en detalle. (If you do not understand the label, find someone to explain it to you in detail.)

CAUSES IRREVERSIBLE EYE DAMAGE.

HARMFUL IF SWALLOWED OR INHALED.

MAY CAUSE SKIN IRRITATION.

Do not get in eyes, on skin or on clothing. Avoid breathing vapor or spray mist.

FIRST AID: IF IN EYES, immediately flush with plenty of water for at least 15 minutes. Get medical attention. **IF ON SKIN,** immediately flush with plenty of water. **IF SWALLOWED,** this product will cause gastrointestinal tract irritation. Immediately dilute by swallowing water or milk. Get medical attention. **NOTE TO PHYSICIAN:** Probable mucosal damage may contraindicate the use of gastric lavage. **IF INHALED,** remove individual to fresh air. Get medical attention if breathing difficulty develops.

Personal Protective Equipment (PPE)
Applicators and other handlers must wear: long-sleeved shirt and long pants, waterproof gloves, shoes plus socks and protective eyewear Discard clothing and other absorbent materials that have been drenched or heavily contaminated with this product's concentrate. Do not reuse them. Follow manufacturer's instructions for cleaning/maintaining PPE. If no such instructions for washables, use detergent and hot water. Keep and wash PPE separately from other laundry.

When handlers use closed systems, enclosed cabs, or aircraft in a manner that meets the requirements listed in the Worker Protection Standard (WPS) for agricultural pesticides [40 CFR 170.240 (d)(4-6)], the handler PPE requirements may be reduced or modified as specified in the WPS.

User Safety Recommendations

Users should:

- Wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet.
- Remove clothing immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing.

In case of an emergency involving this product,
Call Collect, day or night, (314) 694-4000.

Environmental Hazards

Do not apply directly to water, or to areas where surface water is present or to intertidal areas below the mean high water mark. Do not contaminate water when disposing of equipment washwaters.

Physical or Chemical Hazards

Spray solutions of this product should be mixed, stored and applied using only stainless steel, aluminum, fiberglass, plastic or plastic-lined steel containers.

DO NOT MIX, STORE OR APPLY THIS PRODUCT OR SPRAY SOLUTIONS OF THIS PRODUCT IN GALVANIZED STEEL OR UNLINED STEEL (EXCEPT STAINLESS STEEL) CONTAINERS OR SPRAY TANKS. This product or spray solutions of this product react with such containers and tanks to product hydrogen gas which may form a highly combustible gas mixture. This gas mixture could flash or explode, causing serious personal injury. If ignited by open flame, spark, welder's torch, lighted cigarette or other ignition source.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in any manner inconsistent with its labeling. For any requirements specific to your State or Tribe, consult the agency responsible for pesticide regulations.

Agricultural Use Requirements

Use this product only in accordance with its labeling and with the Worker Protection Standard, 40 CFR part 170. Refer to supplemental labeling under "Agricultural Use Requirements" in the Directions for Use section for information about this standard.

Non-Agricultural Use Requirements

The requirements in this box apply to uses of this product that are NOT within the scope of the Worker Protection Standard for agricultural pesticides (40 CFR part 170). The WPS applies when this product is used to produce agricultural plants on farms, forests, nurseries or greenhouses.
Keep people and pets off treated areas until spray solution has dried.

Storage and Disposal

Do not contaminate water, foodstuffs, feed or seed by storage or disposal.

DISPOSAL: Wastes resulting from the use of this product that cannot be used or chemically reprocessed should be disposed of in a landfill approved for pesticide disposal or in accordance with applicable Federal, state or local procedures.

Emptied container retains vapor and product residue. Observe all labeled safeguards until container is cleaned, reconditioned or destroyed.

Triple rinse emptied bulk container. Then offer for recycling or reconditioning, or dispose of in a manner approved by state and local authorities.

ACTIVE INGREDIENT:	
*Glyphosate, N-(phosphonomethyl)glycine, in the form of its isopropylamine salt	41.0%
INERT INGREDIENTS:	59.0%
	100.0%

*Contains 480 grams per litre or 4 pounds per U.S. gallon of the active ingredient glyphosate, in the form of its isopropylamine salt. Equivalent to 356 grams per litre or 3 pounds per U.S. gallon of the acid, glyphosate.

This product is protected by U.S. Patent No. 4,405,531. Other patents pending. No license granted under any non-U.S. patents.

EPA Reg. No. 524-339

LOT NO. PACKER NET GAL.

EPA Est. 524-IA-1

21167W1-1M

NOTIFICATION

NOV 1 2 1998

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EPA Reg. No. 524-339

LOT NO. PACKER NET GAL.

EPA Est. 524-IA-1

21167W1-1M

MONSANTO
Food · Health · Hope™

MONSANTO COMPANY
600 13TH STREET, N.W.
SUITE 660
WASHINGTON, D.C. 20005
TEL: (202) 783-2460
FAX: (202) 783-2468

November 4, 1998

Hand Delivered

Office of Pesticide Programs
Document Processing Center (NOTIF)
U. S. Environmental Protection Agency
Room 266A, Crystal Mall #2
1921 Jefferson Davis Highway
Arlington, VA 22202

Attention: Mr. James A. Tompkins (7505C)
Team Leader (25)

Subject: EPA Reg. No. 524-339
Notification of New Brand Name: MON 78087 Herbicide

Dear Mr. Tompkins:

Monsanto wishes to begin to notify the Agency that we will utilize a new alternate brand name for the product registered as EPA Registration No. 524-339. Enclosed please find five (5) copies of label text bearing the brand name **MON 78087 Herbicide**, identified by Print Plate 21167W1-1M. This brand will be used to label shipments of bulk berbicide for the purpose of repackaging into end-use containers. Under separate cover, Monsanto has requested approval of an alternate Confidential Statement of Formula under this same registration number which would be associated with this brand name when approved.

If you have any questions on this matter please feel free to contact me through Dr. Russell P. Schneider or directly at 314-694-1582.

Sincerely,

Stephen J. Watten
Manager, Registrations

cc: R. P. Schneider
D. Fee-White

MONSANTO

Food · Health · Hope™

MONSANTO COMPANY
600 13TH STREET, N.W.
SUITE 660
WASHINGTON, D.C. 20005
TEL: (202) 783-2460
FAX: (202) 783-2468

January 14, 1999

Hand Delivered

Office of Pesticide Programs
Document Processing Center (NOTIF)
U. S. Environmental Protection Agency
Room 266A, Crystal Mall #2
1921 Jefferson Davis Highway
Arlington, VA 22202

Attention: Mr. James A. Tompkins (7505C)
Team Leader (25)

Subject: MON 78087 Herbicide (EPA Reg. No. 524-339)
Submission of Final Printed Labels: 4-Nov-98 Notification
Manufacturing Use Bulk Label

Dear Mr. Tompkins:

On 4-Nov-1998, Monsanto notified EPA that we would use a new brand name "MON 78087 Herbicide" for the purpose of bulk shipments of manufacturing-use product intended for export. Enclosed for your files are five (5) final printed labels based on the new name. The label is identified by Print Plate No. 21167W1-53/M and dated 1999.

The printed label differs from the draft label submitted on 4-Nov-98 because we have omitted the "Agricultural Use Requirements" and "Non-Agricultural Use Requirements" boxes that were included incorrectly in the draft submission. Since this is a manufacturing-use product which does not have Directions for Use describing application to plants, it is outside the scope of Worker Protection Standard, and these boxes are not needed. All other text remains unchanged and is consistent with that approved on the brand names Shackle C or Exchange which are also used on this registration number. The incorrect draft label text was never used in commerce.

If you have any questions on this matter please feel free to contact me through Dr. Russell P. Schneider or directly at 314-694-1582 or by fax at 314-694-4028.

Sincerely,

Stephen J. Wratten
Manager, Registrations

cc: R. P. Schneider
D. Fee-White

Please read instructions on reverse before completing form.

Form Approved. OMB No. 2070-0060. Approval expires 05-31-98

EPA

United States
Environmental Protection Agency
Washington, DC 20460

☐ Registration
☐ Amendment
☒ Other

OPP Identifier Number: 250889

Application for Pesticide - Section I

1. Company/Product Number: 524-339

2. EPA Product Manager: Mr. James Tompkins

3. Proposed Classification: ☒ None ☐ Restricted

4. Company/Product (Name): MON 78087 Herbicide

PM#: 25

5. Name and Address of Applicant *(Include ZIP Code)*:
Monsanto Company
600 13th Street, N.W., Suite 660
Washington, DC 20005

☐ *Check if this is a new address*

6. **Expedited Review.** In accordance with FIFRA Section 3(c)(3)(b)(i), my product is similar or identical in composition and labeling to:
EPA Reg. No. _____
Product Name _____

Section - II

☐ Amendment - Explain below.
☐ Resubmission in response to Agency letter dated _____
☐ Notification - Explain below.
☒ Final printed labels in response to Agency letter dated 11/4/98 Notification
☐ "Me Too" Application.
☐ Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

Section - III

1. Material This Product Will Be Packaged In:

Child-Resistant Packaging: ☐ Yes* ☐ No
** Certification must be submitted*

Unit Packaging: ☐ Yes ☐ No
If "Yes" Unit Packaging wgt. / No. per container

Water Soluble Packaging: ☐ Yes ☐ No
If "Yes" Package wgt / No. per container

2. Type of Container: ☐ Metal ☐ Plastic ☐ Glass ☐ Paper ☐ Other (Specify) _____

3. Location of Net Contents Information: ☐ Label ☐ Container

4. Size(s) Retail Container

5. Location of Label Directions: ☐ On Label ☐ On Labeling accompanying product

6. Manner in Which Label is Affixed to Product: ☐ Lithograph ☐ Paper glued ☐ Stenciled ☐ Other _____

Section - IV

1. Contact Point *(Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)*

Name: Dr. Russell P. Schneider
Title: Agricultural Regulation Director
Telephone No. (Include Area Code): (202) 783-2460

Certification

I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

2. Signature: Stephen J. Wratten
3. Title: Manager, Registrations
4. Typed Name: Stephen J. Wratten, Ph.D.
5. Date: January 14, 1999

6. Date Application Received (Stamped)

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- Remove clothing immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing.

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Call Collect, day or night, (314) 694-4000.

Environmental Hazards

Do not apply directly to water, or to areas where surface water is present or to intertidal areas below the mean high water mark. Do not contaminate water when disposing of equipment washwaters.

Physical or Chemical Hazards

Spray solutions of this product should be mixed, stored and applied using only stainless steel, aluminum, fiberglass, plastic or plastic-lined steel containers.

DO NOT MIX, STORE OR APPLY THIS PRODUCT OR SPRAY SOLUTIONS OF THIS PRODUCT IN GALVANIZED STEEL OR UNLINED STEEL (EXCEPT STAINLESS STEEL) CONTAINERS OR SPRAY TANKS. This product or spray solutions of this product react with such containers and tanks to product hydrogen gas which may form a highly combustible gas mixture. This gas mixture could flash or explode, causing serious personal injury. If ignited by open flame, spark, welder's torch, lighted cigarette or other ignition source.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in any manner inconsistent with its labeling. For any requirements specific to your State or Tribe, consult the agency responsible for pesticide regulations.

Storage and Disposal

Do not contaminate water, foodstuffs, feed or seed by storage or disposal.

DISPOSAL: Wastes resulting from the use of this product that cannot be used or chemically reprocessed should be disposed of in a landfill approved for pesticide disposal or in accordance with applicable Federal, state or local procedures.

Emptied container retains vapor and product residue. Observe all labeled safeguards until container is cleaned, reconditioned or destroyed.

Triple rinse emptied bulk container. Then offer for recycling or reconditioning, or dispose of in a manner approved by state and local authorities.

FOR REPACKAGING INTO HERBICIDES ONLY.

ACTIVE INGREDIENT:	
*Glyphosate, N-(phosphonomethyl)glycine, in the form of its isopropylamine salt	41.0%
INERT INGREDIENTS:	59.0%
	100.0%

*Contains 480 grams per litre or 4 pounds per U.S. gallon of the active ingredient glyphosate, in the form of its isopropylamine salt. Equivalent to 356 grams per litre or 3 pounds per U.S. gallon of the acid, glyphosate.

This product is protected by U.S. Patent No. 4,405,531. Other patents pending. No license granted under any non-U.S. patents.

EPA Reg. No. 524-339

51

LOT NO. PACKER NET GAL.

EPA Est. 524-IA-1

21167W1-1/53M

MON 78087

Herbicide by Monsanto

Water soluble herbicide for nonselective control of many annual and perennial weeds.
Avoid contact with foliage, green stems, or fruit of crops, desirable plants and trees, since severe injury or destruction may result.

PRECAUTIONARY STATEMENTS

Hazards to Humans and Domestic Animals

Keep out of reach of children.

DANGER! PELIGRO!

Si usted no entiende la etiqueta, busque a alguien para que se la explique a usted en detalle. (If you do not understand the label, find someone to explain it to you in detail.)

CAUSES IRREVERSIBLE EYE DAMAGE.

HARMFUL IF SWALLOWED OR INHALED.

MAY CAUSE SKIN IRRITATION.

Do not get in eyes, on skin or on clothing. Avoid breathing vapor or spray mist.

FIRST AID: IF IN EYES, immediately flush with plenty of water for at least 15 minutes. Get medical attention. **IF ON SKIN,** immediately flush with plenty of water. **IF SWALLOWED,** this product will cause gastrointestinal tract irritation. Immediately dilute by swallowing water or milk. Get medical attention. **NOTE TO PHYSICIAN:** Probable mucosal damage may contraindicate the use of gastric lavage. **IF INHALED,** remove individual to fresh air. Get medical attention if breathing difficulty develops.

Personal Protective Equipment (PPE)

Applicators and other handlers must wear: long-sleeved shirt and long pants, waterproof gloves, shoes plus socks and protective eyewear Discard clothing and other absorbent materials that have been drenched or heavily contaminated with this product's concentrate. Do not reuse them. Follow manufacturer's instructions for cleaning/maintaining PPE. If no such instructions for washables, use detergent and hot water. Keep and wash PPE separately from other laundry.

When handlers use closed systems, enclosed cabs, or aircraft in a manner that meets the requirements listed in the Worker Protection Standard (WPS) for agricultural pesticides [40 CFR 170.240 (d)(4-6)], the handler PPE requirements may be reduced or modified as specified in the WPS.

User Safety Recommendations

Users should:

- Wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet.
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LOT NO. PACKER NET GAL.

EPA Est. 524-IA-1

21167W1-1/53M

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

NOV - 4 1998

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

Mr. Stephen W. Wratten
Monsanto Company
600 13th Street, N.W. Suite 660
Washington, DC 20005

Dear Mr. Wratten:

Subject: MON 78087 Herbicide (Alternate Formulation)
EPA Registration No. 524-339
Your Application Dated October 26, 1998

The scientific review and evaluation of the alternate formulation submitted above have been completed. The requested alternate formulation is acceptable and our records have been modified accordingly.

Sincerely,

Vickie C Walters for
James A. Tompkins
Product Manager 25
Herbicide Branch
Registration Division (7505C)

SUBMISSION REVIEW RECORD

REGISTRATION NUMBER: 524-EIA | 3339 | STATUS: | DATE RECEIVED: MO 10 DAY 21 YR 98

1. IS A PUBLICATION NECESSARY? ☐ YES ☐ NO

4. PETITION NO.

5. RECEIVED BY TEAM: MO | DAY | YR

6. METHOD OF SUPPORT ☐ 5A ☐ 5B ☐ 5C

7. PRODUCT MANAGER: NO.

8. PROJECTED RETURN: MO | DAY | YR

9. DATE FILED: 11/4/98

10. DATE PUBLISHED

11. ACTION TYPE: alternate formulation 345

CODE | 12. OUTGOING DATE: MO | DAY | YR

REQUIRED	REVIEW TYPE CODE	REVIEW TYPE	REVIEWER CODE (Initials)	SIGNATURE OF REVIEWER	COMMENT CODE	DATE REVIEW COMPLETED: MO	DAY	YR
	A	REVIEWABILITY TEAM						
	B	PRODUCT MANAGER TEAM EFFICACY REVIEW						
	C	PRODUCT MANAGER TEAM HUMAN SAFETY REVIEW						
	D	PRODUCT MANAGER TEAM ENVIRONMENTAL SAFETY REVIEW						
	E	PRODUCT MANAGER TEAM RESUBMISSION REVIEW						
	F	PRODUCT MANAGER		VKW VAC		11	04	98
	G	INTERAGENCY REFERRAL						
	H	COST-BENEFIT REVIEW						
	I	PUBLIC COMMENTS REVIEW						
	J	EEB BRANCH INSECTICIDE EFFICACY						
	K	EEB BRANCH HERBICIDE EFFICACY						
	L	EEB BRANCH FUNGICIDE EFFICACY						
	M	EEB BRANCH ANTIMICROBIAL EFFICACY						
	N	EEB BRANCH DISINFECTANT EFFICACY						
	O	CHEMISTRY BRANCH RESIDUE CHEMISTRY						
	P	EEB BRANCH ENVIRONMENTAL CHEMISTRY						
	Q	TOXICOLOGY BRANCH HUMAN SAFETY						
	R	EEB BRANCH ENVIRONMENTAL SAFETY						
	S							
	T							

PRODUCT MANAGER SIGNATURE

TYPE OF RESPONSE | CODE

EPA Form 8570-18 (3-78)

A B

Please read instructions on reverse before completing form.

Form Approved. OMB No. 2070-0060. Approval expires 05-31-98

EPA

United States
Environmental Protection Agency
Washington, DC 20460

☐ Registration
☒ Amendment
☐ Other

OPP Identifier Number: 250857

Application for Pesticide - Section I

1. Company/Product Number	2. EPA Product Manager	3. Proposed Classification
524-339	Mr. James Tompkins	☒ None ☐ Restricted
4. Company/Product (Name) MON 78087 Herbicide	**PM#** 25	

5. Name and Address of Applicant *(Include ZIP Code)*
Monsanto Company
600 13th Street, N.W., Suite 660
Washington, DC 20005

☐ *Check if this is a new address*

6. Expedited Review. In accordance with FIFRA Section 3(c)(3)(b)(i), my product is similar or identical in composition and labeling to:

EPA Reg. No. _____

Product Name _____

Section - II

☒ Amendment - Explain below.
☐ Resubmission in response to Agency letter dated _____
☐ Notification - Explain below.
☐ Final printed labels in response to Agency letter dated _____
☐ "Me Too" Application.
☐ Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

Alternate CSF for MON 78087 Herbicide

Section - III

1. Material This Product Will Be Packaged In:

Child-Resistant Packaging	Unit Packaging	Water Soluble Packaging	2. Type of Container
☐ Yes* ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Metal ☐ Plastic ☐ Glass ☐ Paper ☐ Other (Specify) _____
* *Certification must be submitted*	If "Yes" Unit Packaging wgt. / No. per container	If "Yes" Package wgt / No. per container	

3. Location of Net Contents Information	4. Size(s) Retail Container	5. Location of Label Directions
☐ Label ☐ Container		☐ On Label ☐ On Labeling accompanying product

6. Manner in Which Label is Affixed to Product ☐ Lithograph ☐ Paper glued ☐ Stenciled ☐ Other _____

Section - IV

1. Contact Point *(Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)*

Name	Title	Telephone No. (Include Area Code)
Dr. Russell P. Schneider	Agricultural Regulation Director	(202) 783-2460

Certification

I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

2. Signature	3. Title	6. Date Application Received
Stephen J. Wratten	Manager, Registrations	(Stamped)
4. Typed Name Stephen J. Wratten, Ph.D.	**5. Date** October 26, 1998	

EPA Form 8570-1 (Rev. 8-94) Previous editions are obsolete. White - EPA File Copy (original) Yellow - Applicant Copy

PAPERWORK REDUCTION ACT NOTICE and INSTRUCTIONS

PAPERWORK REDUCTION ACT NOTICE: Public reporting burden for this collection of information is estimated to average 0.85 hour per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to Chief, Information Policy Branch, (2136), U.S. Environmental Protection Agency, 401 M Street, SW, Washington, DC 20460.

INSTRUCTIONS: This form is to be used for all applications for new registration, end use reregistration, amendment, resubmission, to applications for notifications, final printed labeling, reregistration, etc. In order to process an application for a new registration submitted on this form, the following material must accompany the application:

1. Certification with Respect to Citation of Data (EPA Form 8570-29). [If not exempted by 40 CFR 152.81 (b) (4)];
2. Confidential Statement of Formula (EPA Form 8570-4);
3. Formulator's Exemption Statement (EPA Form 8570-27);
4. Five copies of draft labeling;
5. Three copies of any data submitted;
6. Authorization letter where applicable;
7. Matrices where applicable.

Submission of Labeling - Labeling should first be submitted in the form of draft labels with all applications for new registration. Such draft labels may be in the form of typed label text on 8.5 x 11 inch paper for submission or a mockup of the proposed label. If prepared for mockup, it should be constructed in a way as to facilitate storage in an 8.5 x 11 inch file. Mockup labels significantly smaller than 8.5 x 11 inches should be mounted on 8 x 11 inch paper for submission.

Submission of Data - Data submitted in support of this application must be submitted in accordance with PR Notice 86-5.

SPECIFIC INSTRUCTIONS: Please read the instructions listed below before completing this application. First determine the type of registration action, listed in Block A, for which you are submitting this application. For applications submitted in connection with New Registration actions, Sections I, III, and IV must be completed by the applicant. For applications submitted in connection with amended reregistration actions, resubmissions, notifications, reregistrations, etc., Sections I, II, and IV must be completed by the applicant.

Block A - Check the appropriate action for which you are submitting this form.

SECTION I - This section must be completed, as applicable, for all registration actions.

1. **Company/Product Number** - Insert your Company Number, if one has been assigned by EPA. This number may have been assigned to you as a basic registrant, a distributor, or as an establishment. If your product is registered, insert the Product Number.
2. **EPA Product Manager** - If known, fill in the name and PM number of the EPA Product Manager.
3. **Proposed Classification** - Specify the proposed classification of this product.
4. **Product Name** - Enter the complete product name of this pesticide as it will appear on the label. The name must be specific to this product only. Duplication of names is not permitted among products of the same company. Do not include any brand name or company line designations.
5. **Name and Address of Applicant** - The name of the firm or person and address shown in your application is the person or firm to whom the registration will be issued. If you are acting in behalf of another party, you must submit authorization from that party to act for them in registration matters. An applicant not residing in the United States must have an authorized agent residing in the United States to act for them in all registration matters. The name and complete mailing address of such an agent must accompany this application.
6. **Expedited Review** - FIFRA section 3 (c) 3 (B) provides for expedited review of applications for registration, or amendments to existing registrations, that are similar or identicol to other pesticide products that are currently registered with the EPA. In order for your application to be eligible for expedited review, you must provide us with the EPA Registration Number and product name of the product you believe is similar to or identical to your product. The product must be similar or identical in both formulation and labeled uses.

SECTION II - This section must be completed for all applications submitted to amend the registration only of a currently registered product (Amendment), for a resubmission in response to an Agency letter, for notifications to the Agency, for the submission of final printed labeling, for reregistration and for any other action that pertains to a specific EPA-registered product. This section is not to be used for a new application for registration.

1. **Subject of submission** - Check the applicable block and provide the Agency letter date if appropriate. Provide a brief explanation of the purpose(s) for the submission, such as "the addition of a site, pest or crop (specify)"; "amend the Confidential Statement of Formula by..."; "reregistration submission"; "general label revision of use directions." Attach a separate page if additional space is needed.

SECTION III (Packaging and Container Information) - This Section must be completed for all applications submitted in connection with new registration or applicable amendments.

1. **Type of Packaging** - Check the appropriate block if your product will be packaged in the indicated packaging types. Indicate the size of the individual packets and number per retail container.
2. **Type of Retail Container** - Indicate type of container in which product will be marketed.
3. **Location of Net Contents** - Indicate the location of the net contents information for your product.
4. **Size(s) of Retail Container** - Specify the net contents of all retail containers for your product.
5. **Location of Use Directions** - Indicate the location of the use directions for your product.
6. **Manner in which label is affixed to product** - Indicated the method product label is attached to retail container.

SECTION IV (Contact Point) - This Section must be completed for all applications for Registration actions, i.e., new products registration, resubmission, "me-too," reregistration, etc.

1-5. Self-explanatory.
6. EPA Use Only.

A

B

MONSANTO

Food • Health • Hope™

MONSANTO COMPANY
600 13TH STREET, N.W.
SUITE 660
WASHINGTON, D.C. 20005
TEL: (202) 783-2460
FAX: (202) 783-2468

October 26, 1998

Hand Delivered

Office of Pesticide Programs
Document Processing Center (AMEND)
U. S. Environmental Protection Agency
Room 266A, Crystal Mall #2
1921 Jefferson Davis Highway
Arlington, VA 22202

Attention: Mr. James A. Tompkins (7505C)
Team Leader (25)

Subject: Alternate CSF for EPA Reg. No. 524-339
MON 78087 Herbicide

Dear Mr. Tompkins:

Shackle C Herbicide and Exchange Herbicide are manufacturing-use products which are registered as source materials in the preparation of other more dilute glyphosate herbicide products. They consist of 41% glyphosate in the form of its isopropylamine salt, combined with surfactant. Compositionally, these two herbicides are identical to the group of brand names registered under 524-308.

The present basic CSF for EPA Reg. No. 524-339 was approved on 27-Jul-1995 (copy enclosed). It is the only CSF presently approved for this registration. At this time, Monsanto submits for Agency review and approval two signed original copies of an alternate CSF for EPA Reg. No. 524-339. This alternate CSF describes a composition with the same content of glyphosate, but slightly less surfactant than the basic CSF. The purpose of this alternate is to produce a differentiated product for export.

The proposed alternate CSF also includes the name "MON 78087 Herbicide" which Monsanto is requesting as an alternate brand name on this registration in a separate letter.

If you have any questions on this matter please feel free to contact me through Dr. Russell P. Schneider or directly at 314-694-1582.

Sincerely,

Stephen J. Wratten
Manager, Registrations

cc: R. P. Schneider
P. De Ryck
J. Nesbit

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

NOV - 4 1998

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

Mr. Stephen W. Wratten
Monsanto Company
600 13th Street, N.W. Suite 660
Washington, DC 20005

Dear Mr. Wratten:

Subject: Exchange Herbicide (Revise Directions for Use)
EPA Registration No. 524-339
Your Application Dated August 11,, 1998

The labeling submitted above is not acceptable. Based on consultation with Office of General Counsel (OGC) the statement "This product may be reformulated or repackaged in accordance with an express written agreement with Monsanto Company and only into a herbicide for use in industrial turf and ornamental sites,...) is not acceptable. A copy of OGC's comments are enclosed for your use.

If acceptance of other changes on this label are needed, submit five (5) copies of revised labeling deleting the unacceptable statement for our review and stamping.

Sincerely,

Vicki K Walters for

James A. Tompkins
Product Manager 25
Herbicide Branch
Registration Division (7505C)

SUBMISSION RECORD	REGISTRATION NUMBER	STATUS	DATE RECEIVED
G	1524-1 3391	I	MO 08 DAY 14 YR 98

3. IS PUBLICATION NECESSARY	4. PETITION NO.	5. RECEIVED BY TEAM
☐ YES ☐ NO		MO DAY YR

6. METHOD OF SUPPORT	7. PRODUCT MANAGER	NO.	8. PROJECTED RETURN
☐ 6A ☐ 6B ☐ 6C			MO DAY YR

9. DATE FILED	10. DATE PUBLISHED	11. ACTION TYPE	CODE	12. OUTGOING DATE
9/21/98		Update Storage + Disposal + Directions for Use for "Exchange		MO DAY YR

REVIEW SEQ	REVIEW TYPE CODE	REVIEW TYPE	REVIEWER CODE (Initials)	SIGNATURE OF REVIEWER	COMMENT CODE	DATE REVIEW COMPLETED MO	DAY	YR
	A	REVIEWABILITY TEAM						
	B	PRODUCT MANAGER TEAM EFFICACY REVIEW						
	C	PRODUCT MANAGER TEAM HUMAN SAFETY REVIEW						
	D	PRODUCT MANAGER TEAM ENVIRONMENTAL SAFETY REVIEW						
	E	PRODUCT MANAGER TEAM RESUBMISSION REVIEW						
	F	PRODUCT MANAGER		VKW	obj	09	21	98
	G	INTERAGENCY REFERRAL		See attached comments				
	H	COST-BENEFIT REVIEW		from OGC.				
	I	PUBLIC COMMENTS REVIEW						
	J	EEB BRANCH INSECTICIDE EFFICACY						
	K	EEB BRANCH HERBICIDE EFFICACY						
	L	EEB BRANCH FUNGICIDE EFFICACY						
	M	EEB BRANCH ANTIMICROBIAL EFFICACY						
	N	EEB BRANCH DISINFECTANT EFFICACY						
	O	CHEMISTRY BRANCH RESIDUE CHEMISTRY						
	P	EEB BRANCH ENVIRONMENTAL CHEMISTRY						
	Q	TOXICOLOGY BRANCH HUMAN SAFETY						
	R	EEB BRANCH ENVIRONMENTAL SAFETY						
	S							
	T							

PRODUCT MANAGER SIGNATURE	TYPE OF RESPONSE	CODE

EPA Form 8570-18 (3-78)

Jim Tompkins
10/27/98 10:43 AM

To: Vickie Walters/DC/USEPA/US@EPA
cc:
Subject: Labeling Question -Reply

---------- Forwarded by Jim Tompkins/DC/USEPA/US on 10/27/98 11:47 AM ----------

DYNER.MARK
10/27/98 10:14 AM

To: Tompkins.Jim
cc:
Subject: Labeling Question -Reply

[redacted]

>>> <Tompkins.Jim@epamail.epa.gov> 10/22/98, 03:12pm >>>
Monsanto has on a number of their technical labels " This product may be
reformulated or repackaged only in accordance with an express written agreement with Monsanto Company, and only into herbicide for use in industrial, turf, and ornamental sites.....

Don Stubbs has indicated that Monsanto must delete this statement from
their labels because there is nothing in FIFRA that says that a registrant
must have an expressed written agreement before they can reformulate

Privileged attorney-client communication

a
technical into end use product that is registered with the Agency.
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would also appear to be using the Federal Government to assist
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prohibiting competitors from producing end use products.

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the label.

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that we could put into a letter telling Monsanto to take this
statement off
the label that will be legally defensible when Monsanto objects.

A

Please read instructions on reverse before completing form.

Form Approved. OMB No. 2070-0060. Approval expires 2-28-95

EPA

United States
Environmental Protection Agency
Washington, DC 20460

- [ ] Registration
- [x] Amendment
- [ ] Other

OPP Identifier Number: 261437

Application for Pesticide - Section I

1. Company/Product Number: 524-339

2. EPA Product Manager: Mr. James Tompkins
PM#: 25

3. Proposed Classification: [x] None [ ] Restricted

4. Company/Product (Name): Exchange Herbicide

5. Name and Address of Applicant *(Include ZIP Code)*
Monsanto Company
600 13th Street, N.W., Suite 660
Washington, DC 20005
[ ] *Check if this is a new address*

6. **Expedited Reveiw.** In accordance with FIFRA Section 3(c)(3)(b)(i), my product is similar or identical in composition and labeling to:
EPA Reg. No. 5547723
Product Name _____

Section - II

- [x] Amendment - Explain below.
- [ ] Resubmission in response to Agency letter dated _____
- [ ] Notification - Explain below.
- [ ] Final printed labels in repsonse to Agency letter dated _____
- [ ] "Me Too" Application.
- [ ] Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

Submission of update disposal statement and directions for use for Exchange Herbicide

Section - III

1. Material This Product Will Be Packaged In:

Child-Resistant Packaging	Unit Packaging		Water Soluble Packaging		2. Type of Container
[ ] Yes [ ] No	[ ] Yes [ ] No		[ ] Yes [ ] No		[ ] Metal [ ] Plastic [ ] Glass [ ] Paper [ ] Other (Specify)
* *Certification must be submitted*	If "Yes" Unit Packaging wgt.	No. per container	If "Yes" Package wgt	No. per container	

3. Location of Net Contents Information: [ ] Label [ ] Container

4. Size(s) Retail Container

5. Location of Label Directions [ ]

6. Manner in Which Label is Affixed to Product: [ ] Lithograph [ ] Paper glued [ ] Stenciled [ ] Other _____

Section - IV

1. Contact Point *(Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)*

Name	Title	Telephone No. (Include Area Code)
Russell P. Schneider, Ph.D.	Agricultural Regulation Director	(202) 783-2460

Certification

I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowlingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

6. Date Application Received (Stamped)

2. Signature: Stephen J. Wratten

3. Title: Manager, Registrations

4. Typed Name: Stephen J. Wratten, Ph.D.

5. Date: August 11, 1998

EPA Form 8570-1 (Rev. 3-94) Previous editions are obsolete. White - EPA File Copy (original) Yellow - Applicant Copy

PAPERWORK REDUCTION ACT NOTICE and INSTRUCTIONS

PAPERWORK REDUCTION ACT NOTICE: Public reporting burden for this collection of information is estimated to average 0.85 hour per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to Chief, Information Policy Branch, PM-223, U.S. Environmental Protection Agency, 401 M Street, SW, Washington, DC 20460; and to the Office of Information and Regulatory Affairs, Office of Management and Budget, Washington, DC 20503.

INSTRUCTIONS: This form is to be used for all applications for new registration, end use reregistration, amendment, resubmission, to applications for notifications, final printed labeling, reregistration, etc. In order to process an application for a new registration submitted on this form, the following material must accompany the application:

1. Certification with Respect to Citation of Data (EPA Form 8570-29). [If not exempted by 40 CFR 152.81 (b) (4)];
2. Confidential Statement of Formula (EPA Form 8570-4);
3. Formulator's Exemption Statement (EPA Form 8570-27);
4. Five copies of draft labeling;
5. Three copies of any data submitted;
6. Authorization letter where applicable;
7. Matrices where applicable.

Submission of Labeling - Labeling should first be submitted in the form of draft labels with all applications for new registration. Such draft labels may be in the form of typed label text on 8.5 x 11 inch paper or a mockup of the proposed label. If prepared as a mockup, it should be constructed in such a way as to facilitate storage in an 8.5 x 11 inch file. Mockup labels significantly smaller than 8.5 x 11 inches should be mounted on 8.5 x 11 inch paper for submission.
Submission of Data - Data submitted in support of this application must be submitted in accordance with PR Notice 86-5.

SPECIFIC INSTRUCTIONS: Please read the instructions listed below before completing this application. First determine the type of registration action, listed in Block A, for which you are submitting this application. For applications submitted in connection with New Registration actions, Sections I, III, and IV must be completed by the applicant. For applications submitted in connection with amended registration actions, resubmissions, notifications, reregistrations, etc., Sections I, II, and IV must be completed by the applicant.
Block A - Check the appropriate action for which you are submitting this form.

SECTION I - This section must be completed, as applicable, for all registration actions.

1. Company/Product Number - Insert your Company Number, if one has been assigned by EPA. This number may have been assigned to you as a basic registrant, a distributor, or as an establishment. If your product is registered, insert the Product Number.
2. EPA Product Manager - If known, fill in the name and PM number of the EPA Product Manager.
3. Proposed Classification - Specify the proposed classification of this product.
4. Product Name - Enter the complete product name of this pesticide as it will appear on the label. The name must be specific to this product only. Duplication of names is not permitted among products of the same company. Do not include any brand name or company line designations.
5. Name and Address of Applicant - The name of the firm or person and address shown in your application is the person or firm to whom the registration will be issued. If you are acting in behalf of another party, you must submit authorization from that party to act for them in registration matters. An applicant not residing in the United States must have an authorized agent residing in the United States to act for them in all registration matters. The name and complete mailing address of such an agent must accompany this application.
6. Expedited Review - FIFRA section 3 (c) 3 (B) provides for expedited review of applications for registration, or amendments to existing registrations, that are similar or identical to other pesticide products that are currently registered with the EPA. In order for your application to be eligible for expedited review, you must provide us with the EPA Registration Number and product name of the product you believe is similar to or identical to your product. The product must be similar or identical in both formulation and labeled uses.

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1. Subject of submission - Check the applicable block and provide the Agency letter date if appropriate. Provide a brief explanation of the purpose(s) for the submission, such as "the addition of a site, pest or crop (specify)"; "amend the Confidential Statement of Formula by..."; "reregistration submission"; general label revision of use directions." Attach a separate page if additional space is needed.

SECTION III (Packaging and Container Information) - This Section must be completed for all applications submitted in connection with new registration or applicable amendments.

1. Type of Packaging - Check the appropriate block if your product will be packaged in the indicated packaging types. Indicate the size of the individual packets and number per retail container.
2. Type of Retail Container - Indicate type of container in which product will be marketed.
3. Location of Net Contents - Specify the net contents of all retail containers for your product.
4. Size(s) of Retail Container - Specify the net contents of all retail containers for your product.
5. Location of Use Directions - Indicate the location of the use directions for your product.
6. Manner in which label is affixed to product - Indicate the method product label is attached to retail container.

SECTION IV (Contact Point) - This Section must be completed for all applications for Registration actions, i.e., new products, registration, resubmission, "me-too," reregistration, etc.

1-5. Self-explanatory.
6. EPA Use Only

EXCHANGE®

HERBICIDE ~~BY~~ ~~Monsanto~~

Read the entire label before using this product.

~~Read "LIMIT OF WARRANTY AND LIABILITY" before buying or using. If terms are not acceptable, return at once unopened.~~

REFORMULATION OR REPACKAGING IS PROHIBITED; EXCEPT IN ACCORDANCE WITH AN EXPRESS WRITTEN AGREEMENT WITH MONSANTO COMPANY.

PRECAUTIONARY STATEMENTS

Hazards to Humans and Domestic Animals

Keep out of reach of children.

DANGER!

CAUSES IRREVERSIBLE EYE DAMAGE.
HARMFUL IF SWALLOWED OR INHALED.
MAY CAUSE SKIN IRRITATION.

Do not get in eyes, on skin or on clothing.
Wear goggles or face shield.
Avoid breathing vapor or spray mist.
Wash thoroughly with soap and water after handling.
Remove contaminated clothing and wash before reuse.

FIRST AID: IF IN EYES, immediately flush with plenty of water for at least 15 minutes. Get medical attention.

If ON SKIN, immediately flush with plenty of water. Remove contaminated clothing. Wash clothing before reuse.

IF SWALLOWED, this product will cause gastrointestinal tract irritation. Immediately dilute by swallowing water or milk. Get medical attention.

NOTE TO PHYSICIAN: Probable mucosal damage may contraindicate the use of gastric lavage.

IF INHALED, remove individual to fresh air. Get medical attention if breathing difficulty develops.

In case of an emergency involving this product,
Call Collect, day or night, (314) 694-4000.

Environmental Hazards

Do not apply directly to water, to areas where surface water is present or to intertidal areas below the mean high water mark. Do not contaminate water when disposing of equipment washwaters.

Physical or Chemical Hazards

Solutions of this product should be mixed and stored using only stainless steel, aluminum, fiberglass, plastic or plastic-lined steel containers.

DO NOT MIX OR STORE THIS PRODUCT OR SOLUTIONS OF THIS PRODUCT IN GALVANIZED STEEL OR UNLINED STEEL (EXCEPT STAINLESS STEEL) CONTAINERS OR SPRAY TANKS. This product or solutions of this product react with such containers and tanks to produce hydrogen gas which may form a highly combustible gas mixture. This gas mixture could flash or explode, causing serious personal injury, if ignited by open flame, spark, welder's torch, lighted cigarette or other ignition source.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in any manner inconsistent with its labeling.

This product may be reformulated or repackaged only in accordance with an express written agreement with Monsanto Company, and only into a herbicide for use in industrial, turf, and ornamental sites; residential sites; or some or all of the following cropping systems: vegetables, citrus, pome fruits, stone fruits, small fruits and berries, tree nuts, cereal grains, animal grasses and forages, tropical fruits, asparagus, avocado, banana, cotton, cranberry, fig, grapes, kiwi, mango, okra, papaya, peanut, persimmon, pineapple, sugarcane and watercress, as set forth in that agreement.

Storage and Disposal

Do not contaminate water, foodstuffs, feed or seed by storage or disposal.

DISPOSAL: Wastes of this pesticide may cause irreversible eye damage and may be dangerous. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance.

Emptied container retains vapor and product residue. Observe all labeled safeguards until container is ~~cleaned, reconditioned, or~~ destroyed. ~~DO NOT CUT OR WELD ON OR NEAR THIS CONTAINER.~~ Do not reuse container. Triple rinse container. Then puncture and dispose of in a sanitary landfill, or by incineration, or, if allowed by state and local authorities, by burning. If burned, stay out of smoke.

~~**FOR MANUFACTURING, REFORMULATION AND REPACKAGING AS A HERBICIDE ONLY.**~~

ACTIVE INGREDIENT:	
*Glyphosate, N-(phosphonomethyl)glycine, in the form of its isopropylamine salt	41.0%
INERT INGREDIENTS:	59.0%
	100.0%

*Contains 480 grams per litre or 4 pounds per U.S. Gallon of the active ingredient glyphosate, in the form of its isopropylamine salt. Equivalent to 356 grams per litre or 3 pounds per U.S. gallon of the acid, glyphosate.

This product is protected by U.S. Patent No. 4,405,531. Other patents pending. No license granted under any non-U.S. patent(s).

~~LIMIT OF WARRANTY AND LIABILITY~~

~~This Company warrants that this product conforms to the chemical description on this label. NO OTHER EXPRESS WARRANTY OR IMPLIED WARRANTY OF FITNESS FOR PARTICULAR PURPOSE OR MERCHANTABILITY IS MADE. This warranty is also subject to the conditions and limitations stated herein.~~

~~Buyer and all users shall promptly notify this Company of any claims whether based in contract, negligence, strict liability, other tort or otherwise.~~

~~Buyer and all users are responsible for all loss or damage from use or handling which results from conditions beyond the control of this Company, including, but not limited to, uses or applications in any manner not explicitly set forth in this label or application to or contact with desirable vegetation.~~

~~THE EXCLUSIVE REMEDY OF THE USER OR BUYER AND THE LIMIT OF THE LIABILITY OF THIS COMPANY OR ANY OTHER SELLER FOR ANY AND ALL LOSSES, INJURIES OR DAMAGES RESULTING FROM THE USE OR HANDLING OF THIS PRODUCT (INCLUDING CLAIMS BASED IN CONTRACT, NEGLIGENCE, STRICT LIABILITY, OTHER TORT OR OTHERWISE) SHALL BE THE PURCHASE PRICE PAID BY THE USER OR BUYER FOR THE QUANTITY OF THIS PRODUCT INVOLVED, OR AT THE ELECTION OF THIS COMPANY OR ANY OTHER SELLER, THE REPLACEMENT OF SUCH QUANTITY, OR, IF NOT ACQUIRED BY PURCHASE, REPLACEMENT OF SUCH QUANTITY. IN NO EVENT SHALL THIS COMPANY OR ANY OTHER SELLER BE LIABLE FOR ANY INCIDENTAL, CONSEQUENTIAL OR SPECIAL DAMAGES.~~

~~Buyer and all users are deemed to have accepted the terms of this LIMIT OF WARRANTY AND LIABILITY which may not be varied by any verbal or written agreement.~~

Exchange is a registered trademark of Monsanto Company.

ST. LOUIS, MISSOURI 63167 U.S.A.
EPA Reg. No. 524-339

EPA Est. 524-LA-1 21006W2-2/53L

NET 54 U.S. GAL.

(01) 0 00 70183 50409 1

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MONSANTO

Food · Health · Hope™

MONSANTO COMPANY
600 13TH STREET, N.W.
SUITE 660
WASHINGTON, D.C. 20005
TEL: (202) 783-2460
FAX: (202) 783-2468

August 11, 1998

Hand Delivered

Office of Pesticide Programs
Document Processing Center (AMEND)
U. S. Environmental Protection Agency
Room 266A, Crystal Mall #2
1921 Jefferson Davis Highway
Arlington, VA 22202

Attention: Mr. James A. Tompkins (7505C)
Team Leader (25)

Subject: Exchange Herbicide (EPA Reg. No. 524-339)
Update Disposal Statement and Directions for Use

Dear Mr. Tompkins:

Exchange Herbicide is a manufacturing use product (MUP) which can be used by formulators to prepare glyphosate herbicides. The present label text was approved by the Agency on 20-Oct-1997 in conjunction with its reregistration. At this time, Monsanto proposes new draft label text for Agency review and approval to make the following changes:

- In EPA's label manual, registrants of MUP are directed to include a statement specifying the use sites for which end use products can be prepared using the MUP. Monsanto now proposes to utilize the same statement that is presently approved for MON 0139 62% Technical Solution (524-333) on all it's glyphosate MUPs. The existing statements specifying directions for reformulation into herbicides is now redundant and is to be deleted.
- The Limit of Warranty and Liability statement is intended for end-use products rather than MUPs, and is not needed on this label. It is therefore proposed to delete.

- The company name "by Monsanto" is removed from the position immediately below the brand name in anticipation of a new company name following completion of our declared intent to merge with American Home Products.
- Exchange is now provided in plastic drums which are intended for single use. Certain statements in the storage and disposal section are intended for steel drums, and are now outdated and proposed for deletion.

If you have any questions on this matter please feel free to contact me through Dr. Russell P. Schneider or directly at 314-694-1582.

Sincerely,

Stephen J. Wratten
Manager, Registrations

cc: R. P. Schneider
D. Fee-White

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

NOV - 4 1998

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

Mr. Stephen W. Wratten
Monsanto Company
600 13th Street, N.W. Suite 660
Washington, DC 20005

Dear Mr. Wratten:

Subject: Shackle C Herbicide (Revise Directions for Use)
EPA Registration No. 524-339
Your Application Dated August 11,, 1998

The labeling submitted above is not acceptable. Based on consultation with Office of General Counsel (OGC) the statement "This product may be reformulated or repackaged in accordance with an express written agreement with Monsanto Company and only into a herbicide for use in industrial turf and ornamental sites,...) is not acceptable. A copy of OGC's comments are enclosed for your use.

If acceptance of other changes on this label are needed, submit five (5) copies of revised labeling deleting the unacceptable statement for our review and stamping.

Sincerely,

James A. Tompkins
Product Manager 25
Herbicide Branch
Registration Division (7505C)

SUBMISSION REVIEW RECORD

REGISTRATION NUMBER: 524-313 | STATUS: | DATE RECEIVED: MO 08 DAY 14 YR 98

3. IS A PUBLICATION NECESSARY? ☐ YES ☐ NO

4. PETITION NO.

5. RECEIVED BY TEAM: MO DAY YR

6. METHOD OF SUPPORT ☐ 6A ☐ 6B ☐ 6C

7. PRODUCT MANAGER: NO.

8. PROJECTED RETURN: MO DAY YR

9. DATE PULLED: 9/22/98

10. DATE PUBLISHED

11. ACTION TYPE: Update active ingredient statement + Directions for Use (Shaklee)

CODE

12. OUTGOING DATE: MO DAY YR

NEW USE	REVIEW TYPE CODE	REVIEW TYPE	REVIEWER CODE (Initials)	SIGNATURE OF REVIEWER	COMMENT CODE	DATE REVIEW COMPLETED MO	DAY	YR
	A	REVIEWABILITY TEAM						
	B	PRODUCT MANAGER TEAM EFFICACY REVIEW						
	C	PRODUCT MANAGER TEAM HUMAN SAFETY REVIEW						
	D	PRODUCT MANAGER TEAM ENVIRONMENTAL SAFETY REVIEW						
	E	PRODUCT MANAGER TEAM RESUBMISSION REVIEW						
	F	PRODUCT MANAGER		300 UKW	obj	01	04	98
	G	INTERAGENCY REFERRAL		see OGC response attached.				
	H	COST-BENEFIT REVIEW						
	I	PUBLIC COMMENTS REVIEW						
	J	EEB BRANCH INSECTICIDE EFFICACY						
	K	EEB BRANCH HERBICIDE EFFICACY						
	L	EEB BRANCH FUNGICIDE EFFICACY						
	M	EEB BRANCH RODENTICIDE EFFICACY						
	N	EEB BRANCH DISINFECTANT EFFICACY						
	O	CHEMISTRY BRANCH RESIDUE CHEMISTRY						
	P	EEB BRANCH ENVIRONMENTAL CHEMISTRY						
	Q	TOXICOLOGY BRANCH HUMAN SAFETY						
	R	EEB BRANCH ENVIRONMENTAL SAFETY						
	S							
	T							

PRODUCT MANAGER SIGNATURE

TYPE OF RESPONSE | CODE

EPA Form 8570-13 (3-78)

Jim Tompkins
10/27/98 10:43 AM

To: Vickie Walters/DC/USEPA/US@EPA
cc:
Subject: Labeling Question -Reply

---------- Forwarded by Jim Tompkins/DC/USEPA/US on 10/27/98 11:47 AM ----------

DYNER.MARK
10/27/98 10:14 AM

To: Tompkins.Jim
cc:
Subject: Labeling Question -Reply

[redacted]

Privileged attorney-client communication

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that we could put into a letter telling Monsanto to take this statement off
the label that will be legally defensible when Monsanto objects.

B

Please read instructions on reverse before completing form.

Form Approved. OMB No. 2070-0060. Approval expires 2-28-95

EPA

United States
Environmental Protection Agency
Washington, DC 20460

- [ ] Registration
- [x] Amendment
- [ ] Other

OPP Identifier Number: 261438

Application for Pesticide - Section I

1. Company/Product Number: 524-339

2. EPA Product Manager: Mr. James Tompkins

PM#: 25

3. Proposed Classification: [X] None [ ] Restricted

4. Company/Product (Name): Shackle C Herbicide

5. Name and Address of Applicant *(Include ZIP Code)*:
Monsanto Company
600 13th Street, N.W., Suite 660
Washington, DC 20005

[ ] *Check if this is a new address*

6. **Expedited Reveiw.** In accordance with FIFRA Section 3(c)(3)(b)(i), my product is similar or identical in composition and labeling to:
EPA Reg. No. 5547722

Product Name _____

Section - II

- [x] Amendment - Explain below.
- [ ] Resubmission in response to Agency letter dated _____
- [ ] Notification - Explain below.
- [ ] Final printed labels in repsonse to Agency letter dated _____
- [ ] "Me Too" Application.
- [ ] Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

Submission of update ingredients statement and directions for use for Shackle C Herbicide

Section - III

1. Material This Product Will Be Packaged In:

Child-Resistant Packaging	Unit Packaging	Water Soluble Packaging	2. Type of Container
[ ] Yes [ ] No	[ ] Yes [ ] No	[ ] Yes [ ] No	[ ] Metal [ ] Plastic [ ] Glass [ ] Paper [ ] Other (Specify)
* *Certification must be submitted*	If "Yes" Unit Packaging wgt. / No. per container	If "Yes" Package wgt / No. per container	

3. Location of Net Contents Information: [ ] Label [ ] Container

4. Size(s) Retail Container

5. Location of Label Directions

6. Manner in Which Label is Affixed to Product: [ ] Lithograph [ ] Paper glued [ ] Stenciled [ ] Other _____

Section - IV

1. Contact Point *(Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)*

Name	Title	Telephone No. (Include Area Code)
Russell P. Schneider, Ph.D.	Agricultural Regulation Director	(202) 783-2460

Certification

I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowlingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

2. Signature	3. Title	6. Date Application Received
Stephen J. Wratten	Manager, Registrations	(Stamped)
4. Typed Name: Stephen J. Wratten, Ph.D.	5. Date: August 11, 1998	

EPA Form 8570-1 (Rev. 3-94) Previous editions are obsolete. White - EPA File Copy (original) Yellow - Applicant Copy

PAPERWORK REDUCTION ACT NOTICE and INSTRUCTIONS

PAPERWORK REDUCTION ACT NOTICE: Public reporting burden for this collection of information is estimated to average 0.85 hour per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to Chief, Information Policy Branch, PM-223, U.S. Environmental Protection Agency, 401 M Street, SW, Washington, DC 20460; and to the Office of Information and Regulatory Affairs, Office of Management and Budget, Washington, DC 20503.

INSTRUCTIONS: This form is to be used for all applications for new registration, and use reregistration, amendment, resubmission, to applications for notifications, final printed labeling, reregistration, etc. In order to process an application for a new registration submitted on this form, the following material must accompany the application:

1. Certification with Respect to Citation of Data (EPA Form 8570-29). [If not exempted by 40 CFR 152.81 (b) (4)];
2. Confidential Statement of Formula (EPA Form 8570-4);
3. Formulator's Exemption Statement (EPA Form 8570-27);
4. Five copies of draft labeling;
5. Three copies of any data submitted;
6. Authorization letter where applicable;
7. Matrices where applicable.

Submission of Labeling - Labeling should first be submitted in the form of draft labels with all applications for new registration. Such draft labels may be in the form of typed label text on 8.5 x 11 inch paper or a mockup of the proposed label. If prepared as a mockup, it should be constructed in such a way as to facilitate storage in an 8.5 x 11 inch file. Mockup labels significantly smaller than 8.5 x 11 inches should be mounted on 8.5 x 11 inch paper for submission.
Submission of Data - Data submitted in support of this application must be submitted in accordance with PR Notice 86-5.

SPECIFIC INSTRUCTIONS: Please read the instructions listed below before completing this application. First determine the type of registration action, listed in Block A, for which you are submitting this application. For applications submitted in connection with New Registration actions, Sections I, III, and IV must be completed by the applicant. For applications submitted in connection with amended registration actions, resubmissions, notifications, reregistrations, etc., Sections I, II, and IV must be completed by the applicant.
Block A - Check the appropriate action for which you are submitting this form.

SECTION I - This section must be completed, as applicable, for all registration actions.

1. Company/Product Number - Insert your Company Number, if one has been assigned by EPA. This number may have been assigned to you as a basic registrant, a distributor, or as an establishment. If your product is registered, insert the Product Number.
2. EPA Product Manager - If known, fill in the name and PM number of the EPA Product Manager.
3. Proposed Classification - Specify the proposed classification of this product.
4. Product Name - Enter the complete product name of this pesticide as it will appear on the label. The name must be specific to this product only. Duplication of names is not permitted among products of the same company. Do not include any brand name or company line designations.
5. Name and Address of Applicant - The name of the firm or person and address shown in your application is the person or firm to whom the registration will be issued. If you are acting in behalf of another party, you must submit authorization from that party to act for them in registration matters. An applicant not residing in the United States must have an authorized agent residing in the United States to act for them in all registration matters. The name and complete mailing address of such an agent must accompany this application.
6. Expedited Review - FIFRA section 3 (c) 3 (B) provides for expedited review of applications for registration, or amendments to existing registrations, that are similar or identical to other pesticide products that are currently registered with the EPA. In order for your application to be eligible for expedited review, you must provide us with the EPA Registration Number and product name of the product you believe is similar to or identical to your product. The product must be similar or identical in both formulation and labeled uses.

SECTION II - This section must be completed for all applications submitted to amend the registration only of a currently registered product (Amendment), for a resubmission in response to an Agency letter, for notifications to the Agency, for the submission of final printed labeling, for reregistration and for any other action that pertains to a specific EPA-registered product. This section is not to be used for a new application for registration.

1. Subject of submission - Check the applicable block and provide the Agency letter date if appropriate. Provide a brief explanation of the purpose(s) for the submission, such as "the addition of a site, pest or crop (specify)"; "amend the Confidential Statement of Formula by..."; "reregistration submission"; general label revision of use directions." Attach a separate page if additional space is needed.

SECTION III (Packaging and Container Information) - This Section must be completed for all applications submitted in connection with new registration or applicable amendments.

1. Type of Packaging - Check the appropriate block if your product will be packaged in the indicated packaging types. Indicate the size of the individual packets and number per retail container.
2. Type of Retail Container - Indicate type of container in which product will be marketed.
3. Location of Net Contents - Specify the net contents of all retail containers for your product.
4. Size(s) of Retail Container - Specify the net contents of all retail containers for your product.
5. Location of Use Directions - Indicate the location of the use directions for your product.
6. Manner in which label is affixed to product - Indicate the method product label is attached to retail container.

SECTION IV (Contact Point) - This Section must be completed for all applications for Registration actions, i.e., new products registration, resubmission, "me-too," reregistration, etc.

1-5. Self-explanatory.
6. EPA Use Only.

MONSANTO

Food · Health · Hope™

MONSANTO COMPANY
600 13TH STREET, N.W.
SUITE 660
WASHINGTON, D.C. 20005
TEL: (202) 783-2460
FAX: (202) 783-2468

August 11, 1998

Hand Delivered

Office of Pesticide Programs
Document Processing Center (AMEND)
U. S. Environmental Protection Agency
Room 266A, Crystal Mall #2
1921 Jefferson Davis Highway
Arlington, VA 22202

Attention: Mr. James A. Tompkins (7505C)
Team Leader (25)

Subject: Shackle C Herbicide (EPA Reg. No. 524-339)
Update Ingredients Statement and Directions for Use

Dear Mr. Tompkins:

Shackle C Herbicide is a manufacturing use product (MUP) which can be used by formulators to prepare glyphosate herbicides. The present label text was approved by the Agency on 20-Oct-1997 in conjunction with its reregistration. At this time, Monsanto proposes new draft label text for Agency review and approval to make the following changes:

- In EPA's label manual, registrants of MUP are directed to include a statement specifying the use sites for which end use products can be prepared using the MUP. Monsanto now proposes to utilize the same statement that is presently approved for MON 0139 62% Technical Solution (524-333) on all it's glyphosate MUPs. Other existing statements specifying directions for formulation into herbicides are now redundant and are to be deleted.
- All Monsanto glyphosate labels are intended to identify the active ingredient by the term "glyphosate" and by it's chemical name. The proposed change will make this ingredient statement consistent with other labels.

- The company name "by Monsanto" is removed from the position immediately below the brand name in anticipation of a new company name following completion of our declared intent to merge with American Home Products. The company name still appears at the bottom of the label, and the outdated term "Agricultural Products" is deleted from the name.

If you have any questions on this matter please feel free to contact me through Dr. Russell P. Schneider or directly at 314-694-1582.

Sincerely,

Stephen J. Wratten
Manager, Registrations

cc: R. P. Schneider
D. Fee-White

CONCENTRATE

SHACKLE® C

Herbicide ~~by~~ ~~Monsanto~~

It is a violation of Federal law to use this product in any manner inconsistent with its labeling.

Read the entire label before using this product.

PRECAUTIONARY STATEMENTS

Hazards to Humans and Domestic Animals

Keep out of reach of children.

DANGER!

CAUSES IRREVERSIBLE EYE DAMAGE.
HARMFUL IF SWALLOWED OR INHALED.
MAY CAUSE SKIN IRRITATION.
Do not get in eyes, on skin or on clothing.
Wear goggles or face shield.
Avoid breathing vapor or spray mist.
Wash thoroughly with soap and water after handling.
Remove contaminated clothing and wash before reuse.

FIRST AID: IF IN EYES, immediately flush with plenty of water for at least 15 minutes. Get medical attention.

If ON SKIN, immediately flush with plenty of water. Remove contaminated clothing. Wash clothing before reuse.

IF SWALLOWED, this product will cause gastrointestinal tract irritation. Immediately dilute by swallowing water or milk. Get medical attention.

NOTE TO PHYSICIAN: Probable mucosal damage may contraindicate the use of gastric lavage.

IF INHALED, remove individual to fresh air. Get medical attention if breathing difficulty develops.

In case of an emergency involving this product,
Call Collect, day or night, (314) 694-4000.

Environmental Hazards

Do not apply directly to water, to areas where surface water is present or to intertidal areas below the mean high water mark. Do not contaminate water when disposing of equipment washwaters.

Physical or Chemical Hazards

Solutions of this product should be mixed and stored only in stainless steel, aluminum, fiberglass, plastic and plastic-lined steel containers.

DO NOT MIX, STORE OR APPLY THIS PRODUCT OR SPRAY SOLUTIONS OF THIS PRODUCT IN GALVANIZED STEEL OR UNLINED STEEL (EXCEPT STAINLESS STEEL) CONTAINERS OR SPRAY TANKS. This product or spray solutions of this product react with such containers and tanks to produce hydrogen gas which may form a highly combustible gas mixture. This gas mixture could flash or explode, causing serious personal injury, if ignited by open flame, spark, welder's torch, lighted cigarette or other ignition source.

DIRECTIONS FOR USE

For formulation of products (not to exceed 10% active ingredient) for weed and grass control ~~in industrial, residential and ornamental areas~~.

This product may be reformulated or repackaged only in accordance with an express written agreement with Monsanto Company, and only into a herbicide for use in industrial, turf, and ornamental sites; residential sites; or some or all of the following cropping systems: vegetables, citrus, pome fruits, stone fruits, small fruits and berries, tree nuts, cereal grains, animal grasses and forages, tropical fruits, asparagus, avocado, banana, cotton, cranberry, fig, grapes, kiwi, mango, okra, papaya, peanut, persimmon, pineapple, sugarcane and watercress, as set forth in that agreement.

Storage and Oisposal

Do not contaminate water, foodstuffs, feed or seed by storage or disposal.

DISPOSAL: Wastes of this pesticide may cause irreversible eye damage and may be dangerous. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance.

Emptied container retains vapor and product residue. Observe all labeled safeguards until container is cleaned, reconditioned, or destroyed.

Triple rinse emptied bulk container. Then offer for recycling or reconditioning, or dispose of in a manner approved by state and local authorities.

~~FOR HERBICIDE FORMULATION ONLY~~

ACTIVE INGREDIENT:	
*Glyphosate, N-(phosphonomethyl)glycine, in the form of its isopropylamine salt ~~of glyphosate~~	41.0%
INERT INGREDIENTS:	59.0%
	100.0%

*Contains 480 grams per litre or 4 pounds per U.S. Gallon of the active ingredient glyphosate, in the form of its isopropylamine salt ~~of N-(phosphonomethyl)glycine~~. Equivalent to 356 grams per litre or 3 pounds per U.S. gallon of the acid, glyphosate.

This protected by U.S. Patent No. 4,405,531. Other patents pending. No license granted under any non-U.S. patent(s).

Shackle is a registered trademark of Monsanto Company.

EPA Reg. No. 524-339

LOT NO. PACKER NET LB.

EPA Est. 239-IA-3

MONSANTO COMPANY, ~~AGRICULTURAL PRODUCTS~~, ST. LOUIS, MISSOURI 63167, U.S.A.

U.S. ENVIRONMENTAL PROTECTION AGENCY
Office of Pesticide Programs
Registration Division (H7505C)
401 "M" St., S.W.
Washington, D.C. 20460

EPA Reg. Number: 524-339

Date of Issuance: OCT 29 1997

Term of Issuance: Unconditional

Name of Pesticide Product: Shackle C Herbicide Exchange Herbicide

NOTICE OF PESTICIDE:
___ Registration
_x_ Reregistration

(under FIFRA, as amended)

Name and Address of Registrant (include ZIP Code):

Monsanto Company
700 14th Street, N.W. Suite #1100
Washington, D.C. 20005

Note: Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Registration Division prior to use of the label in commerce. In any correspondence on this product always refer to the above EPA registration number.

On the basis of information furnished by the registrant, the above named pesticide is hereby registered/reregistered under the Federal Insecticide, Fungicide and Rodenticide Act.

Registration is in no way to be construed as an endorsement or recommendation of this product by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.

Based on your response to the Reregistration Eligibility Document, EPA has reregistered the product listed above. Enclosed is a copy of your stamped "Acceptable". This action is taken under the authority of section 4(g)(2)(C) of the Federal Insecticide, Fungicide and Rodenticide Act, as amended. Reregistration under this section does not eliminate the need for conditinual reassessment of pesticides. EPA may require submission of data at any time to maintain registration of your product.

VKW

Signature of Approving Official:

Date: 10-25-97

EPA Form 8570-6

PRECAUTIONARY STATEMENTS

Hazards to Humans and Domestic Animals

Keep out of reach of children.

DANGER!

CAUSES IRREVERSIBLE EYE DAMAGE.
HARMFUL IF SWALLOWED OR INHALED.
MAY CAUSE SKIN IRRITATION.
Do not get in eyes, on skin or on clothing.
Wear goggles or face shield.
Avoid breathing vapor or spray mist.
Wash thoroughly with soap and water after handling.
Remove contaminated clothing and wash before reuse.

FIRST AID: IF IN EYES, immediately flush with plenty of water for at least 15 minutes. Get medical attention.

IF ON SKIN, immediately flush with plenty of water. Remove contaminated clothing. Wash clothing before reuse.

IF SWALLOWED, this product will cause gastrointestinal tract irritation. Immediately dilute by swallowing water or milk. Get medical attention.

NOTE TO PHYSICIAN: Probable mucosal damage may contraindicate the use of gastric lavage.

IF INHALED, remove individual to fresh air. Get medical attention if breathing difficulty develops.

In case of an emergency involving this product,
Call Collect, day or night, (314) 694-4000.

Environmental Hazards

Do not apply directly to water, to areas where surface water is present or to intertidal areas below the mean high water mark. Do not contaminate water when disposing of equipment washwaters.

Physical or Chemical Hazards

Solutions of this product should be mixed and stored using only stainless steel, aluminum, fiberglass, plastic or plastic-lined steel containers.

DO NOT MIX OR STORE THIS PRODUCT OR SOLUTIONS OF THIS PRODUCT IN GALVANIZED STEEL OR UNLINED STEEL (EXCEPT STAINLESS STEEL) CONTAINERS OR SPRAY TANKS. This product or solutions of this product react with such containers and tanks to produce hydrogen gas which may form a highly combustible gas mixture. This gas mixture could flash or explode, causing serious personal injury, if ignited by open flame, spark, welder's torch, lighted cigarette or other ignition source.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in any manner inconsistent with its labeling.

Storage and Disposal

Do not contaminate water, foodstuffs, feed or seed by storage or disposal.

DISPOSAL: Wastes of this pesticide may cause irreversible eye damage and may be dangerous. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance.

Emptied container retains vapor and product residue. Observe all labeled safeguards until container is cleaned, reconditioned or destroyed. DO NOT CUT OR WELD ON OR NEAR THIS CONTAINER.

Do not reuse container. Triple rinse container. Then puncture and dispose of in a sanitary landfill, or by incineration, or, if allowed by state and local authorities, by burning. If burned, stay out of smoke.

FOR MANUFACTURING, REFORMULATION AND REPACKAGING AS A HERBICIDE ONLY.

LIMIT OF WARRANTY AND LIABILITY

This Company warrants that this product conforms to the chemical description on this label. NO OTHER EXPRESS WARRANTY OR IMPLIED WARRANTY OF FITNESS FOR PARTICULAR PURPOSE OR MERCHANTABILITY IS MADE. This warranty is also subject to the conditions and limitations stated herein.

Buyer and all users shall promptly notify this Company of any claims whether based in contract, negligence, strict liability, other tort or otherwise.

Buyer and all users are responsible for all loss or damage from use or handling which results from conditions beyond the control of this Company, including, but not limited to, uses or applications in any manner not explicitly set forth in this label or application to or contact with desirable vegetation.

THE EXCLUSIVE REMEDY OF THE USER OR BUYER, AND THE LIMIT OF THE LIABILITY OF THIS COMPANY OR ANY OTHER SELLER FOR ANY AND ALL LOSSES, INJURIES OR DAMAGES RESULTING FROM THE USE OR HANOLING OF THIS PRODUCT (INCLUDING CLAIMS BASED IN CONTRACT, NEGLIGENCE, STRICT LIABILITY, OTHER TORT OR OTHERWISE) SHALL BE THE PURCHASE PRICE PAID BY THE USER OR BUYER FOR THE QUANTITY OF THIS PROOUCT INVOLVED, OR, AT THE ELECTION OF THIS COMPANY OR ANY OTHER SELLER, THE REPLACEMENT OF SUCH QUANTITY, OR, IF NOT ACQUIRED BY PURCHASE, REPLACEMENT OF SUCH QUANTITY. IN NO EVENT SHALL THIS COMPANY OR ANY OTHER SELLER BE LIABLE FOR ANY INCIDENTAL, CONSEQUENTIAL OR SPECIAL DAMAGES.

Buyer and all users are deemed to have accepted the terms of this LIMIT OF WARRANTY AND LIABILITY which may not be varied by any verbal or written agreement.

Product protected by U.S. Patent No. 4,405,531. Other patents are pending. No license granted under any non-U.S. patent(s).

EXCHANGE®

HERBICIDE BY Monsanto

Read the entire label before using this product.

Read "LIMIT OF WARRANTY AND LIABILITY" before buying or using. If terms are not acceptable, return at once unopened.

REFORMULATION OR REPACKAGING IS PROHIBITED; EXCEPT IN ACCORDANCE WITH AN EXPRESS WRITTEN AGREEMENT WITH MONSANTO COMPANY.

Keep out of reach of children.

DANGER! Read precautions on side panel.

In case of an emergency involving this product,
Call Collect, day or night, (314) 694-4000.

NET 54 U.S. GAL.

ACTIVE INGREDIENT:

*Glyphosate, N-(phosphonomethyl)glycine, in the form of its isopropylamine salt	41.0%
INERT INGREDIENTS:	59.0%
	100.0%

*Contains 480 grams per litre or 4 pounds per U.S. gallon of the active ingredient glyphosate, in the form of its isopropylamine salt. Equivalent to 356 grams per litre or 3 pounds per U.S. gallon of the acid, glyphosate.

®Registered trademark of Monsanto Company.

MONSANTO COMPANY
ST. LOUIS, MISSOURI 63167 U.S.A.

EPA Reg. No. 524-339

EPA Est. 524-LA-1

21006-J1-2/53L

ACCEPTED
OCT 29 1997
Under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, for the pesticide registered under EPA Reg. No. 524-339

(01) 0 00 70183 50409 1

CONCENTRATE

Shackle® C

Herbicide by Monsanto

For formulation of products (not to exceed 10% active ingredient) for weed and grass control in industrial, residential and ornamental areas

ACCEPTED

OCT 29 1997

Under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, for the pesticide registered under EPA Reg. No. 524-339

It is a violation of Federal law to use this product in any manner inconsistent with its labeling.
Read the entire label before using this product.

PRECAUTIONARY STATEMENTS

Hazards to Humans and Domestic Animals

Keep out of reach of children.

DANGER!

CAUSES IRREVERSIBLE EYE DAMAGE.
HARMFUL IF SWALLOWED OR INHALED.
MAY CAUSE SKIN IRRITATION.
Do not get in eyes, on skin or on clothing.
Wear goggles or face shield.
Avoid breathing vapor or spray mist.
Wash thoroughly with soap and water after handling.
Remove contaminated clothing and wash before reuse.

FIRST AID: IF IN EYES, immediately flush with plenty of water for at least 15 minutes. Get medical attention.
IF ON SKIN, immediately flush with plenty of water. Remove contaminated clothing. Wash clothing before reuse.
IF SWALLOWED, this product will cause gastrointestinal tract irritation. Immediately dilute by swallowing water or milk. Get medical attention.
NOTE TO PHYSICIAN: Probable mucosal damage may contraindicate the use of gastric lavage.
IF INHALED, remove individual to fresh air. Get medical attention if breathing difficulty develops.

In case of an emergency involving this product, Call Collect, day or night, (314) 694-4000.

Environmental Hazards

Do not apply directly to water, to areas where surface water is present or to intertidal areas below the mean high water mark. Do not contaminate water when disposing of equipment washwaters.

Physical or Chemical Hazards

Solutions of this product should be mixed and stored only in stainless steel, aluminum, fiberglass, plastic and plastic-lined steel containers.

DO NOT MIX, STORE OR APPLY THIS PRODUCT OR SPRAY SOLUTIONS OF THIS PRODUCT IN GALVANIZED STEEL OR UNLINED STEEL (EXCEPT STAINLESS STEEL) CONTAINERS OR SPRAY TANKS.

This product or spray solutions of this product react with such containers and tanks to produce hydrogen gas which may form a highly combustible gas mixture. This gas mixture could flash or explode, causing serious personal injury, if ignited by open flame, spark, welder's torch, lighted cigarette or other ignition source.

Storage and Disposal

Do not contaminate water, foodstuffs, seed or feed by storage or disposal.

DISPOSAL: Wastes of this pesticide may cause irreversible eye damage and may be dangerous. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance.

Emptied container retains vapor and product residue. Observe all labeled safeguards until container is cleaned, reconditioned or destroyed

Triple rinse emptied bulk containers. Then offer for recycling or reconditioning, or dispose of in a manner approved by state and local authorities.

FOR HERBICIDE FORMULATION ONLY

ACTIVE INGREDIENT:	
*Isopropylamine salt of glyphosate	41.0%
INERT INGREDIENTS:	59.0%
	100.0%

*Contains 480 grams per liter or 4 pounds per U.S. gallon of the active ingredient isopropylamine salt of N-(phosphonomethyl) glycine. Equivalent to 356 grams per liter or 3 pounds per U. S. gallon of the acid, glyphosate.

This product is protected by U.S. Patent No. 4,405,531. Other patents are pending. No license granted under any non-U.S. patent(s).

®Shackle is a registered trademark of Monsanto Company.

MONSANTO COMPANY
AGRICULTURAL PRODUCTS
ST. LOUIS, MISSOURI 63167 U.S.A.

EPA Reg. No. 524-339

NET U.S. GAL.

EPA Est. No. 239-IA-3 21074T1-1FT

87

SUBMISSION REVIEW RECORD

REGISTRATION NUMBER: 1524-133 | STATUS: | DATE RECEIVED: MO 08 DAY 08 YR 97

3. IS PUBLICATION NECESSARY? ☐ YES ☐ NO

4. PETITION NO.

5. RECEIVED ON TERM: MO DAY YR

6. METHOD OF SUPPORT: ☐ 2A ☐ 2B ☐ 2C

7. PRODUCT MANAGER: NO.

8. PROJECTED RETURN: MO DAY YR

9. DATE PULLED: 10/6/97

10. DATE PUBLISHED

11. ACTION TYPE: Labels for Reregs 655

CODE | 12. OUTGOING DATE: MO DAY YR

REVIEW SEQ	REVIEW PERSONNEL CODE	REVIEW TYPE	REVIEWER CODE (Initials)	SIGNATURE OF REVIEWER	COMMENT CODE	DATE REVIEW COMPLETED MO	DAY	YR
	A	REVIEWABILITY TEAM						
	B	PRODUCT MANAGER TEAM EFFICACY REVIEW						
	C	PRODUCT MANAGER TEAM HUMAN SAFETY REVIEW						
	D	PRODUCT MANAGER TEAM ENVIRONMENTAL SAFETY REVIEW						
	E	PRODUCT MANAGER TEAM RESUBMISSION REVIEW						
	F	PRODUCT MANAGER		UKW	NAC	10	16	97
	G	INTERAGENCY REFERRAL		Company says				
	H	COST-BENEFIT REVIEW		formulation is				
	I	PUBLIC COMMENTS REVIEW		exact to 524-308				
	J	EEB BRANCH INSECTICIDE EFFICACY		which causes Danger				
	K	EEB BRANCH HERBICIDE EFFICACY		appropriate Language				
	L	EEB BRANCH FUNGICIDE EFFICACY						
	M	EEB BRANCH ANTIMICROBIAL EFFICACY						
	N	EEB BRANCH DISINFECTANT EFFICACY						
	O	CHEMISTRY BRANCH RESIDUE CHEMISTRY						
	P	EEB BRANCH ENVIRONMENTAL CHEMISTRY						
	Q	TOXICOLOGY BRANCH HUMAN SAFETY						
	R	EEB BRANCH ENVIRONMENTAL SAFETY						
	S							
	T							

PRODUCT MANAGER SIGNATURE

TYPE OF RESPONSE | CODE

EPA Form 8570-18 (3-78)

CONCENTRATE

Shackle® C

Herbicide by Monsanto

For formulation of products (not to exceed 10% active ingredient)
for weed and grass control in industrial, residential and ornamental areas.

It is a violation of Federal law to use this product in any manner inconsistent with its labeling.
Read the entire label before using this product.

PRECAUTIONARY STATEMENTS

Hazards to Humans and Domestic Animals

Keep out of reach of children.

DANGER!

CAUSES IRREVERSIBLE EYE DAMAGE.
HARMFUL IF SWALLOWED OR INHALED.
MAY CAUSE SKIN IRRITATION.
Do not get in eyes, on skin or on clothing.
Wear goggles or face shield.
Avoid breathing vapor or spray mist.
Wash thoroughly with soap and water after handling.
Remove contaminated clothing and wash before reuse.

FIRST AID: IF IN EYES, immediately flush with plenty of water for at least 15 minutes. Get medical attention.
IF ON SKIN, immediately flush with plenty of water. Remove contaminated clothing. Wash clothing before reuse.
IF SWALLOWED, this product will cause gastrointestinal tract irritation. Immediately dilute by swallowing water or milk. Get medical attention.
NOTE TO PHYSICIAN: Probable mucosal damage may contraindicate the use of gastric lavage.
IF INHALED, remove individual to fresh air. Get medical attention if breathing difficulty develops.

In case of an emergency involving this product, Call Collect, day or night, (314) 694-4000.

Environmental Hazards

Do not apply directly to water, to areas where surface water is present or to intertidal areas below the mean high water mark. Do not contaminate water when disposing of equipment washwaters.

Physical or Chemical Hazards

Solutions of this product should be mixed and stored only in stainless steel, aluminum, fiberglass, plastic and plastic-lined steel containers.

DO NOT MIX, STORE OR APPLY THIS PRODUCT OR SPRAY SOLUTIONS OF THIS PRODUCT IN GALVANIZED STEEL OR UNLINED STEEL (EXCEPT STAINLESS STEEL) CONTAINERS OR SPRAY TANKS.

This product or spray solutions of this product react with such containers and tanks to produce hydrogen gas which may form a highly combustible gas mixture. This gas mixture could flash or explode, causing serious personal injury, if ignited by open flame, spark, welder's torch, lighted cigarette or other ignition source.

Storage and Disposal

Do not contaminate water, foodstuffs, seed or feed by storage or disposal.

DISPOSAL: Wastes of this pesticide may cause irreversible eye damage and may be dangerous. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance.

Emptied container retains vapor and product residue. Observe all labeled safeguards until container is cleaned, reconditioned or destroyed

Triple rinse emptied bulk containers. Then offer for recycling or reconditioning, or dispose of in a manner approved by state and local authorities.

FOR HERBICIDE FORMULATION ONLY

ACTIVE INGREDIENT:	
*Isopropylamine salt of glyphosate	41.0%
INERT INGREDIENTS:	59.0%
	100.0%

*Contains 480 grams per liter or 4 pounds per U.S. gallon of the active ingredient isopropylamine salt of N-(phosphonomethyl) glycine. Equivalent to 356 grams per liter or 3 pounds per U. S. gallon of the acid, glyphosate.

This product is protected by U.S. Patent No. 4,405,531. Other patents are pending. No license granted under any non-U.S. patent(s).

®Shackle is a registered trademark of Monsanto Company.

MONSANTO COMPANY
AGRICULTURAL PRODUCTS
ST. LOUIS, MISSOURI 63167 U.S.A.

EPA Reg. No. 524-339

NET U.S. GAL.

EPA Est. No. 239-IA-3 21074T1-1FT

Monsanto

Monsanto Company
Suite 1100
700 14th Street, N.W.
Washington, D.C. 20005

August 6, 1997

Hand Delivered

Office of Pesticide Programs
Document Processing Center
U.S. Environmental Protection Agency
Room 266A, Crystal Mall #2
1921 Jefferson Davis Highway
Arlington, VA 22202

Attention: Mr. James A. Tompkins (7505C)
Team Leader (25)

Subject: **Shackle® C Herbicide (EPA Reg. No. 524-339)**
Exchange® Herbicide (EPA Reg. No. 524-339)
Precautionary Language
Your Letter Dated 14-Jul-97

Dear Mr. Tompkins

In response to your letter dated 14-Jul-97, Monsanto submits the enclosed five (5) copies of final printed labels for Shackle C Herbicide and Exchange Herbicide. They are:

Shackle C Concentrate Bulk label [print plate 21074T1-1FT]
Exchange 54-gal Drum label [print plate 21006U1-2/53L]

It appears that the Agency made a mistake in the Glyphosate RED in Attachment 4 in which the products were grouped in batches; these products (524-339) were incorrectly grouped with 524-454. 524-339 is a manufacturing use product that is identical to Roundup Export Herbicide (524-308), and should have been grouped with the latter Registration Number instead.

The enclosed labels have Precautionary Language that is identical with that stamped by the Agency on 9-Jul-97, when the reregistration of Roundup Export Herbicide was finalized, except for the placement of the PPE statements dictated by WPS. Since Shackle C Herbicide and Exchange Herbicide are Manufacturing Use products, they do not come under the scope of WPS and have the required statements goggle and clothing statements as shown.

Compared to the labels the Agency received in the correspondence dated 10-Oct-94, the present labels contain updated container disposal text and a prohibition against repackaging or reformulation without a written agreement.

Monsanto believes that when the Agency reviews this new information, the reregistration of products under this number can be finalized using the present labels. It would be confusing and potentially risky to have different label signal words and precautionary language for two different containers of material that Monsanto knows are identical.

If you have any questions on this matter please feel free to contact me through Dr. Russell P. Schneider or directly at 314-694-1582.

Sincerely,

Stephen J. Wratten
Manager, Registrations

cc: R. P. Schneider

Please read instructions on reverse before completing form. Form Approved. OMB No. 2070-0060. Approval expires 2-28-95

EPA

United States
Environmental Protection Agency
Washington, DC 20460

☐ Registration
☐ Amendment
☒ Other

OPP Identifier Number: 232049

Application for Pesticide - Section I

1. Company/Product Number: Monsanto / 524-339

2. EPA Product Manager: Mr. James A Tompkins

3. Proposed Classification: ☒ None ☐ Restricted

4. Company/Product (Name): Shackle C & Exchange Herbicides

PM# 25

5. Name and Address of Applicant *(Include ZIP Code)*
Monsanto Co Suite 1100
700 14th St NW
Washington DC 20005
☐ *Check if this is a new address*

6. **Expedited Review.** In accordance with FIFRA Section 3(c)(3)(b)(i), my product is similar or identical in composition and labeling to:
EPA Reg. No. _____
Product Name _____

Section - II

☐ Amendment - Explain below.
☐ Resubmission in response to Agency letter dated _____
☐ Notification - Explain below.
☒ Final printed labels in response to Agency letter dated 14-Jul-97
☐ "Me Too" Application.
☐ Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)
Final Printed Labeling in response to Agency request

Section - III

1. Material This Product Will Be Packaged In:

Child-Resistant Packaging	Unit Packaging		Water Soluble Packaging		2. Type of Container
☐ Yes* ☐ No	☐ Yes ☐ No		☐ Yes ☐ No		☐ Metal ☐ Plastic ☐ Glass ☐ Paper ☐ Other (Specify)
Certification must be submitted	If "Yes" Unit Packaging wgt.	No. per container	If "Yes" Package wgt	No. per container	

3. Location of Net Contents Information: ☐ Label ☐ Container

4. Size(s) Retail Container

5. Location of Label Directions: ☐ On Label ☐ On Labeling accompanying product

6. Manner in Which Label is Affixed to Product: ☐ Lithograph ☐ Paper glued ☐ Stenciled ☐ Other _____

Section - IV

1. Contact Point *(Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)*

Name	Title	Telephone No. (Include Area Code)
Dr. Russell P Schmidt	Ag. Reg. Director	202-383-2866

Certification

I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

2. Signature: Stephen J. Wratten
3. Title: Manager, Registrations
4. Typed Name: Stephen J. Wratten
5. Date: 8/6/97
6. Date Application Received (Stamped)

EPA Form 8570-1 (Rev. 8-94) Previous editions are obsolete. White - EPA File Copy (original) Yellow - Applicant Copy

PAPERWORK REDUCTION ACT NOTICE and INSTRUCTIONS

PAPERWORK REDUCTION ACT NOTICE: Public reporting burden for this collection of information is estimated to average 0.85 hour per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to Chief, Information Policy Branch, (2136), U.S. Environmental Protection Agency, 401 M Street, SW, Washington, DC 20460; and to the Office of Information and Regulatory Affairs, Office of Management and Budget, Washington, DC 20503.

INSTRUCTIONS: This form is to be used for all applications for new registration, and use reregistration, amendment, resubmission, to applications for notifications, final printed labeling, reregistration, etc. In order to process an application for a new registration submitted on this form, the following material must accompany the application:

1. Certification with Respect to Citation of Data (EPA Form 8570-29). [If not exempted by 40 CFR 152.81 (b) (4)];
2. Confidential Statement of Formula (EPA Form 8570-4);
3. Formulator's Exemption Statement (EPA Form 8570-27);
4. Five copies of draft labeling;
5. Three copies of any data submitted;
6. Authorization letter where applicable;
7. Matrices where applicable.

Submission of Labeling - Labeling should first be submitted in the form of draft labels with all applications for new registration. Such draft labels may be in the form of typed label text on 8.5 x 11 inch paper for submission of a mockup of the proposed label. If prepared for mockup, it should be constructed in a way as to facilitate storage in an 8.5 x 11 inch file. Mockup labels significantly smaller than 8.5 x 11 inches should be mounted on 8.5 x 11 inch paper for submission.

Submission of Data - Data submitted in support of this application must be submitted in accordance with PR Notice 86-5.

SPECIFIC INSTRUCTIONS: Please read the instructions listed below before completing this application. First determine the type of registration action, listed in Block A, for which you are submitting this application. For applications submitted in connection with New Registration actions, Sections I, III, and IV must be completed by the applicant. For applications submitted in connection with amended reregistration actions, resubmissions, notifications, reregistrations, etc., Sections I, II, and IV must be completed by the applicant.

Block A - Check the appropriate action for which you are submitting this form.

SECTION I - This section must be completed, as applicable, for all registration actions.

1. **Company/Product Number** - Insert your Company Number, if one has been assigned by EPA. This number may have been assigned to you as a basic registrant, a distributor, or as an establishment. If your product is registered, insert the Product Number.
2. **EPA Product Manager** - If known, fill in the name and PM number of the EPA Product Manager.
3. **Proposed Classification** - Specify the proposed classification of this product.
4. **Product Name** - Enter the complete product name of this pesticide as it will appear on the label. The name must be specific to this product only. Duplication of names is not permitted among products of the same company. Do not include any brand name or company line designations.
5. **Name and Address of Applicant** - The name of the firm or person and address shown in your application is the person or firm to whom the registration will be issued. If you are acting in behalf of another party, you must submit authorization from that party to act for them in registration matters. An applicant not residing in the United States must have an authorized agent residing in the United States to act for them in all registration matters. The name and complete mailing address of such an agent must accompany this application.
6. **Expedited Review** - FIFRA section 3 (c) 3 (B) provides for expedited review of applications for registration, or amendments to existing registrations, that are similar or identical to other pesticide products that are currently registered with the EPA. In order for your application to be eligible for expedited review, you must provide us with the EPA Registration Number and product name of the product you believe is similar to or identical to your product. The product must be similar or identical in both formulation and labeled uses.

SECTION II - This section must be completed for all applications submitted to amend the registration only of a currently registered product (Amendment), for a resubmission in response to an Agency letter, for notifications to the Agency, for the submission of final printed labeling, for reregistration and for any other action that pertains to a specific EPA-registered product. This section is not to be used for a new application for registration.

1. **Subject of submission** - Check the applicable block and provide the Agency letter date if appropriate. Provide a brief explanation of the purpose(s) for the submission, such as "the addition of a site, pest or crop (specify)"; "amend the Confidential Statement of Formula by..."; "reregistration submission"; "general label revision of use directions." Attach a separate page if additional space is needed.

SECTION III (Packaging and Container Information) - This Section must be completed for all applications submitted in connection with new registration or applicable amendments.

1. Type of Packaging - Check the appropriate block if your product will be packaged in the indicated packaging types. Indicate the size of the individual packets and number per retail container.
2. Type of Retail Container - Indicate type of container in which product will be marketed.
3. Location of Net Contents - Indicate the location of the net contents information for your product.
4. Size(s) of Retail Container - Specify the net contents of all retail containers for your product.
5. Location of Use Directions - Indicate the location of the use directions for your product.
6. Manner in which label is affixed to product - Indicated the method product label is attached to retail container.

SECTION IV (Contact Point) - This Section must be completed for all applications for Registration actions, i.e., new products registration, resubmission, "me too," reregistration, etc.

1-5. Self-explanatory.
6. EPA Use Only.

JUL 14 1997

Mr. Stephen J. Wratten
Monsanto Company
700 14th Street, N.W. Suite #1100
Washington, DC 20005

Dear Mr. Wratten:

Subject: Shackle C Herbicide (Reregistration)
EPA Registration No. 524-339
Your Application Dated October 10, 1994 and June 8, 1995

The scientific review and evaluation of the subject information submitted above have been completed. The following are our comments.

1. The revised CSF submitted June 8, 1995 is acceptable.

2. Based on the acute toxicology data referenced for EPA Registration No. 524-454 (Batch 4) the toxicology categories for this product are II for eye irritation, III for acute inhalation, and IV for acute oral, acute dermal, and dermal irritation.

3. The appropriate signal word is "Warning".

4. The recommended Precautionary Statements are as follows.

Causes substantial but temporary eye injury. Harmful if inhaled. Wear goggles or face shield. Do not get in eyes or on clothing. Avoid breathing vapor or spray mist. Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash contaminated clothing before reuse.

5. The recommended Statements of Practical Treatment as follows.

IF ON EYES: Hold eyelids open and flush with steady, gentle stream of water for 15 minutes.

IF SWALLOWED: Call a doctor or get medical attention. Do not induce vomiting or give anything by mouth to an unconscious person. Drink promptly a large quantity of milk, egg white, gelation solution or these are not available, drink large quantities of water. Avoid alcohol.

IF INHALED: Remove victim to fresh air. If not breathing, give artificial respiration, preferably mouth-to-mouth. Get medical attention.

To complete requirements for reregistration, submit five (5) copies of labeling bearing the above changes for review and stamping. Notify the Agency within 30 days from the date of the letter when requested labels will be submitted.

Sincerely,

James A. Tompkins
Product Manager 25
Herbicide Branch
Registration Division (7505C)

Company states by 8/6/87 letter that this should carry same labeling as 524-308 DANGER same formulations and the name.

DP BARCODE: D217910

CASE: 016767 DATA PACKAGE RECORD DATE: 08/02/95
SUBMISSION: S490417 BEAN SHEET Page 1 of 1

* * * CASE/SUBMISSION INFORMATION * * *

CASE TYPE: REGISTRATION ACTION: 675 RESUBMISSION
RANKING : 0 POINTS ()
CHEMICALS: 103601 Glyphosate, isopropylamine salt 41.0000%

ID#: 000524-00339 SHACKLE C HERBICIDE BY MONSANTO
COMPANY: 000524 MONSANTO AGRICULTURAL CO
PRODUCT MANAGER: 25 ROBERT TAYLOR 703-305-6800 ROOM: CM2 241
PM TEAM REVIEWER: EMILY MITCHELL 703-308-8583 ROOM: CS1 1L3
RECEIVED DATE: 06/12/95 DUE OUT DATE: 12/09/95

* * * DATA PACKAGE INFORMATION * * *

DP BARCODE: 217910 EXPEDITE: N DATE SENT: 08/02/95 DATE RET.: / /
CHEMICAL: 103601 Glyphosate, isopropylamine salt
DP TYPE: 001 Submission Related Data Package
CSF: Y LABEL: Y

ASSIGNED TO	DATE IN	DATE OUT	ADMIN DUE DATE: 10/31/95
DIV : RD	/ /	/ /	NEGOT DATE: / /
BRAN: FHB	/ /	/ /	PROJ DATE: / /
SECT: PMT-25	/ /	/ /	
REVR :	/ /	/ /	
CONTR:	/ /	/ /	

* * * DATA REVIEW INSTRUCTIONS * * *

ATTN: Robert Taylor (Karen Hicks) Rm 251
Attached is a completed package for reregistration of product 524-339.
Inclusive:
-Correspondences/Administrative (Registrant's submissions required by RED)
-Acute Toxicity Reviews
-Product Chemistry Reviews

* * * DATA PACKAGE EVALUATION * * *

No evaluation is written for this data package

* * * ADDITIONAL DATA PACKAGES FOR THIS SUBMISSION * * *

DP BC	BRANCH/SECTION	DATE OUT	DUE BACK	INS	CSF	LABEL
217496	RSB/PCRS	07/20/95	10/18/95	Y	Y	N

13 copies

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

Received MAY 16 1996
Mailed To Sheila Schuette
Date MAY 16 1996
By Russ Schneider

MAY 13 1996

Mr. Robert W. Street
Monsanto Company
Suite 1100
700 14th Street, N.W.
Wash., D.C. 20005

File glyphosate RED

Dear Mr. Street:

The Agency has reviewed the product chemistry and precautionary labeling data submitted to support reregistration of the following products:

MON-0139 Technical Solution EPA Reg. No. 524-318
Protocol Herbicide EPA Reg. No. 524-326
Roundup L&G RTU Grass & Weed Killer EPA Reg. No. 524-330
MON 0139 62% Solution EPA Reg. No. 524-333
RODEO Aquatic Herbicide EPA Reg. No. 524-343
Polado L EPA Reg. No. 524-350
Ranger Herbicide EPA Reg. No. 524-382
Shackle Herbicide EPA Reg. No. 524-339
Fallow Master Herbicide EPA Reg. No. 524-390
Glyphosate Technical EPA Reg. No. 524-421
Roundup Herbicide EPA Reg. No. 524-445
Expedite Grass & Weed Plus Residual Herbicide EPA Reg. No. 524-449
Expedite Grass & Weed II Herbicide EPA Reg.No. 524-450
Roundup L&G RTU Fast ACTG Form Grass & Weed Killer
EPA Reg. No. 524-451
Roundup Quik Stik Grass & Weed Killer EPA Reg. No. 524-452

Copies of the reviews are enclosed for your records.

If you have any questions regarding this matter please contact Karen P. Hicks at (703) 305-7037.

Sincerely,

James A. Tompkins, Deputy
Fungicide-Herbicide Branch
Registration Division (7505C)

DATE OUT: JUL 27 1995

SUBJECT: PRODUCT CHEMISTRY REVIEW OF: MP [ ] EP [X]
DP BARCODE No.: 217496 REG./File Symbol No.: 524-339
PRODUCT NAME: Shackle Herbicide by Monsanto, 41% AI

TO: 25 Robert Taylor/Emily Mitchell
Fungicide-Herbicide Branch
Registration Division (H7505C)

FROM: Sami Malak, Chemist Sami Malak
Product Chemistry Review Section
Registration Support Branch/RD (H7505W)

THRU: Harold Podall, Section Head Sami Malak for
Product Chemistry Review Section

BACKGROUND:

In a previous memorandum the following deficiency was cited: "The submitted CSF for this end-use product, Shackle Herbicide by Monsanto, Reg. No. 524-339, EPA received 10/13/94, dated 7/16/80, is unacceptable: The CSF should indicate the upper and lower certified limits of the ingredients."

With this submission, the registrant submitted a revised CSF.

CONCLUSION:

The submitted CSF for this end-use product, Shackle Herbicide by Monsanto, Reg. No. 524-339, EPA received 6/12/95, dated 6/795, is acceptable. All inerts are cleared for non-food uses.

RECOMMENDATIONS:

We recommend for reregistration of this end-use product, Shackle Herbicide by Monsanto, Reg. No. 524-339.

cc: Sami Malak and Central File (Reg. No. 524-339)
H7505W:RD:RSB:PCRS:CS-1:Rm650:Sami Malak:s.m.:07/27/95:703-308-8392:524-339A

A

B

Monsanto

Monsanto Company
Suite 1100
700 14th Street, N.W.
Washington, D.C. 20005

June 8, 1995

Document Processing Desk (RED-RD-PM25)
Office of Pesticide Programs (H7504C)
U.S. Environmental Protection Agency
Room 226A, Crystal Mall 2
1921 Jefferson Davis Highway
Arlington, Virginia 22202

Attention: Mr. Robert J. Taylor
Product Manager (25)

Subject: **Shackle® C Herbicide / Exchange® Herbicide**
EPA Reg. No. 524-339
Glyphosate Reregistration Eligibility Decision (RED)
Submission of Revised Confidential Statement of Formula (CSF)

Dear Sir:

On October 10, 1994, Monsanto submitted a Confidential Statement of Formula (CSF) dated 9/16/80 for Shackle C herbicide (EPA Reg. No. 524-339) to fulfill the product-specific requirements for the reregistration of this product. Monsanto was recently informed that the submitted CSF was unacceptable (a copy of the EPA memorandum is attached) and therefore we are now submitting a revised CSF for Agency review and approval.

As noted under point #2 of the memo, this formulation is identical to the base formulation for Roundup® Export herbicide (EPA Reg. No. 524-308). Accordingly, we have revised the CSF for Shackle C so that it is now essentially identical to that for

Product ingredient source information may be entitled to confidential treatment

Roundup Export. The only difference is that we have updated the surfactant supplier list to reflect the fact that [redacted] was recently purchased by [redacted]

Once approved, this CSF will supersede all previous versions for all brand names under this registration.

If you have any questions regarding this additional information, please contact Russ Schneider or me.

Sincerely,

Sheila A. Schuette

Sheila A. Schuette, Ph.D.
Manager, Regulatory Affairs
(314) 694-7248

cc: Ms. Emily Mitchell / EPA Planning and Reregistration
R.P. Schneider

A B

Please read instructions on reverse before completing form. Form Approved. OMB No. 2070-0060. Approval expires 2-28-95

EPA United States Environmental Protection Agency Washington, DC 20460

[ ] Registration [x] Amendment [ ] Other

OPP Identifier Number: 235650

Application for Pesticide - Section I

1. Company/Product Number: 524-339

2. EPA Product Manager: Robert J. Taylor

3. Proposed Classification: [x] None [ ] Restricted

4. Company/Product (Name): Shackle® C Herbicide

PM# 25

5. Name and Address of Applicant *(Include ZIP Code)*

Monsanto Company
700 14th Street, N.W., Suite 1100
Washington, DC 20005

[ ] *Check if this is a new address*

6. **Expedited Review.** In accordance with FIFRA Section 3(c)(3)(b)(i), my product is similar or identical in composition and labeling to:

EPA Reg. No. _____

Product Name _____

Section - II

[x] Amendment - Explain below.

[ ] Resubmission in response to Agency letter dated _____

[ ] Notification - Explain below.

[ ] Final printed labels in response to Agency letter dated _____

[ ] "Me Too" Application.

[ ] Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

Submission of revised Confidential Statement of Formula

Section - III

1. Material This Product Will Be Packaged In:

Child-Resistant Packaging	Unit Packaging	Water Soluble Packaging	2. Type of Container
[ ] Yes* [x] No	[ ] Yes [x] No	[ ] Yes [x] No	[ ] Metal [x] Plastic [ ] Glass [ ] Paper [ ] Other (Specify)
** Certification must be submitted*	If "Yes" Unit Packaging wgt. / No. per container	If "Yes" Package wgt / No. per container	

3. Location of Net Contents Information: [ ] Label [x] Container

4. Size(s) Retail Container: various

5. Location of Label Directions: [x] On Label [ ] On Labeling accompanying product

6. Manner in Which Label is Affixed to Product: [ ] Lithograph [ ] Paper glued [ ] Stenciled [x] Other vinyl glued

Section - IV

1. Contact Point *(Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)*

Name	Title	Telephone No. (Include Area Code)
Dr. Russell P. Schneider	Agricultural Regulation Director	(202) 783-2460

Certification

I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

6. Date Application Received (Stamped)

2. Signature: Sheila A. Schuette

3. Title: Manager, Regulatory Affairs

4. Typed Name: Sheila A. Schuette, Ph.D.

5. Date: June 8, 1995

EPA Form 8570-1 (Rev. 8-94) Previous editions are obsolete. White - EPA File Copy (original) Yellow - Applicant Copy

PAPERWORK REDUCTION ACT NOTICE and INSTRUCTIONS

PAPERWORK REDUCTION ACT NOTICE: Public reporting burden for this collection of information is estimated to average 0.85 hour per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to Chief, Information Policy Branch, (2136), U.S. Environmental Protection Agency, 401 M Street, SW, Washington, DC 20460; and to the Office of Information and Regulatory Affairs, Office of Management and Budget, Washington, DC 20503.

INSTRUCTIONS: This form is to be used for all applications for new registration, end use reregistration, amendment, resubmission, to applications for notifications, final printed labeling, reregistration, etc. In order to process an application for a new registration submitted on this form, the following material must accompany the application:

1. Certification with Respect to Citation of Data (EPA Form 8570-29). [If not exempted by 40 CFR 152.81 (b) (4)];
2. Confidential Statement of Formula (EPA Form 8570-4);
3. Formula Exemption Statement (EPA Form 8570-27);
4. Five copies of draft labeling;
5. Three copies of any data submitted;
6. Authorization letter where applicable;
7. Matrices where applicable.

Submission of Labeling - Labeling should first be submitted in the form of draft labels with all applications for new registration. Such draft labels may be in the form of typed label text on 8.5 x 11 inch paper for submission or a mockup of the proposed label. If prepared for mockup, it should be constructed in a way as to facilitate storage in an 8.5 x 11 inch file. Mockup labels significantly smaller than 8.5 x 11 inches should be mounted on 8.5 x 11 inch paper for submission.

Submission of Data - Data submitted in support of this application must be submitted in accordance with PR Notice 86-5.

SPECIFIC INSTRUCTIONS: Please read the instructions listed below before completing this application. First determine the type of registration action, listed in Block A, for which you are submitting this application. For applications submitted in connection with New Registration actions, Sections I, III, and IV must be completed by the applicant. For applications submitted in connection with amended reregistration actions, resubmissions, notifications, reregistrations, etc., Sections I, II, and IV must be completed by the applicant.

Block A - Check the appropriate action for which you are submitting this form.

SECTION I - This section must be completed, as applicable, for all registration actions.

1. **Company/Product Number** - Insert your Company Number, if one has been assigned by EPA. This number may have been assigned to you as a basic registrant, a distributor, or as an establishment. If your product is registered, insert the Product Number.
2. **EPA Product Manager** - If known, fill in the name and PM number of the EPA Product Manager.
3. **Proposed Classification** - Specify the proposed classification of this product.
4. **Product Name** - Enter the complete product name of this pesticide as it will appear on the label. The name must be specific to this product only. Duplication of names is not permitted among products of the same company. Do not include any brand name or company line designations.
5. **Name and Address of Applicant** - The name of the firm or person and address shown in your application is the person or firm to whom the registration will be issued. If you are acting in behalf of another party, you must submit authorization from that party to act for them in registration matters. An applicant not residing in the United States must have an authorized agent residing in the United States to act for them in all registration matters. The name and complete mailing address of such an agent must accompany this application.
6. **Expedited Review** - FIFRA section 3 (c) 3 (B) provides for expedited review of applications for registration, or amendments to existing registrations, that are similar or identical to other pesticide products that are currently registered with the EPA. In order for your application to be eligible for expedited review, you must provide us with the EPA Registration Number and product name of the product you believe is similar to or identical to your product. The product must be similar or identical in both formulation and labeled uses.

SECTION II - This section must be completed for all applications submitted to amend the registration only of a currently registered product (Amendment), for a resubmission in response to an Agency letter, for notifications to the Agency, for the submission of final printed labeling, for reregistration and for any other action that pertains to a specific EPA-registered product. This section is not to be used for a new application for registration.

1. **Subject of submission** - Check the applicable block and provide the Agency letter date if appropriate. Provide a brief explanation of the purpose(s) for the submission, such as "the addition of a site, pest or crop (specify)"; "amend the Confidential Statement of Formula by..."; "reregistration submission"; "general label revision of use directions." Attach a separate page if additional space is needed.

SECTION III (Packaging and Container Information) - This Section must be completed for all applications submitted in connection with new registration or applicable amendments.

1. **Type of Packaging** - Check the appropriate block if your product will be packaged in the indicated packaging types. Indicate the size of the individual packets and number per retail container.
2. **Type of Retail Container** - Indicate type of container in which product will be marketed.
3. **Location of Net Contents** - Indicate the location of the net contents information for your product.
4. **Size(s) of Retail Container** - Specify the net contents of all retail containers for your product.
5. **Location of Use Directions** - Indicate the location of the use directions for your product.
6. **Manner in which label is affixed to product** - Indicated the method product label is attached to retail container.

SECTION IV (Contact Point) - This Section must be completed for all applications for Registration actions, i.e., new products registration, resubmission, "me-too," reregistration, etc.

1-5. Self-explanatory.
6. EPA Use Only.

DP BARCODE: D217496

CASE: 016767 DATA PACKAGE RECORD DATE: 07/20/95
SUBMISSION: S490417 BEAN SHEET Page 1 of 1

* * * CASE/SUBMISSION INFORMATION * * *

CASE TYPE: REGISTRATION ACTION: 675 RESUBMISSION
RANKING : 10 POINTS ()
CHEMICALS: 103601 Glyphosate, isopropylamine salt 41.0000%

ID#: 000524-00339 SHACKLE C HERBICIDE BY MONSANTO
COMPANY: 000524 MONSANTO AGRICULTURAL CO
PRODUCT MANAGER: 25 ROBERT TAYLOR 703-305-6800 ROOM: CM2 241
PM TEAM REVIEWER: EMILY MITCHELL 703-308-8583 ROOM: CS1 1L3
RECEIVED DATE: 06/12/95 DUE OUT DATE: 12/09/95

* * * DATA PACKAGE INFORMATION * * *

DP BARCODE: 217496 EXPEDITE: N DATE SENT: 07/20/95 DATE RET.: / /
CHEMICAL: 103601 Glyphosate, isopropylamine salt
DP TYPE: 001 Submission Related Data Package
CSF: Y LABEL: N

ASSIGNED TO	DATE IN	DATE OUT	ADMIN DUE DATE: 10/18/95
DIV : RD	/ /	/ /	NEGOT DATE: / /
BRAN: RSB	/ /	/ /	PROJ DATE: / /
SECT: PCRS	/ /	/ /	
REVR :	/ /	/ /	
CONTR:	/ /	/ /	

* * * DATA REVIEW INSTRUCTIONS * * *

Please review the revised CSF for Registration #524-339.
Attached is also the original review of the CSF that came in with the 8 month response.
If you have any questions please call Emily Mitchell on 308-8583.
Note Please return the reviewed package to PRB 3rd Floor Crystal Station (CRM-Emily Mitchell)

* * * DATA PACKAGE EVALUATION * * *

No evaluation is written for this data package

* * * ADDITIONAL DATA PACKAGES FOR THIS SUBMISSION * * *

DP BC	BRANCH/SECTION	DATE OUT	DUE BACK	INS	CSF	LABEL

PM-25
Robert Taylor
Room 241

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

MEMORANDUM

Subject: EPA Reg. No.: 524-454 (524-339)

From: Mark J. Perry, Biologist
Precautionary Review Section
Registration Support Branch
Registration Division (7505W)

MJP 4-4-95

To: R. Taylor, PM-25 / E. Mitchell
Registration Division (7505C)

Applicant: Monsanto Company
Suite 1100
700 14th St., N.W.
Washington, DC 20005

FORMULATION FROM LABEL:

	% by wt.
Active Ingredient(s): Glyphosate, N-phosphono-methyl)-glycine	41.3
Inert Ingredient(s):	58.7
Total:	100%

BACKGROUND

Monsanto submitted acute oral, acute dermal, acute inhalation, eye irritation, dermal irritation and dermal sensitization studies in response to the Glyphosate RED. The subject product, Roundup RT (EPA Reg. No. 524-454), has been placed in batch 4 of the RED, therefore, the acute data submitted also supports EPA Reg. No. 524-339. The studies were performed by Bio/dynamics and Monsanto and the MRID numbers are 420355-02 through 420355-07.

RECOMMENDATIONS

Previous PRS reviews performed on these studies indicate that the acute oral, acute dermal, acute inhalation, eye irritation, dermal irritation and dermal sensitization studies are acceptable. See attached reviews for study details.

1. Acute Oral; Acceptable / Category IV

2. Acute Dermal; Acceptable / Category IV

3. Acute Inhalation; Acceptable / Category III

4. Eye Irritation; Acceptable / Category II

5. Dermal Irritation; Acceptable / Category IV

6. Dermal Sensitization; Acceptable / Non-sensitizer

LABELING

1. The appropriate signal word is "warning."

2. The recommended Statements of Practical Treatment are as follows:

IF IN EYES: Hold eyelids open and flush with steady, gentle stream of water for 15 minutes. Get medical attention.
IF SWALLOWED: Drink promptly a large quantity of milk, egg whites, gelatin solution, or if these are not available, drink large quantities of water. Avoid alcohol.

IF INHALED: Remove victim to fresh air. If not breathing, give artificial respiration, preferably mouth-to-mouth. Get medical attention.

3. The recommended Precautionary Statements are as follows:

Causes substantial but temporary eye injury. Harmful if inhaled. Wear goggles or face shield. Do not get in eyes or on clothing. Avoid breathing vapor or spray mist. Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash contaminated clothing before reuse.

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524-454

MEMORANDUM:

Subject: EPA File Symbol/EPA Reg. No.:524-ULU

From: Lucy D. Markarian, Biologist 5/14/92
Precautionary Review Section
Registration Support Branch
Registration Division (H7505C)

To: Robert J. Taylor, PM 25
Fungicide-Herbicide Branch
Registration Division (H7505C)

Thru: Thomas C. Ellwanger, Section Head 5/19/92
Precautionary Review Section
Registration Support Branch
Registration Division (H7505C)

Applicant: Monsanto Agricultural Company
800 N. Lindbergh Blvd.
St. Louis, Missouri 63167

FORMULATION FROM LABEL:

Active Ingredient(s)::	% by wt.
Glyphosate: N-(phosphonomethyl) glycine	41.3 %
Inert Ingredient(s):	
.....	58.7 %
Total:	100%

BACKGROUND

The representatives of The Monsanto Agricultural Company, Dr.s Hastings,Schneider and Schuette and Ms Kirk, met with Dr. Ellwanger and L. Markarian of PRS at Monsanto's request to discuss two tests that had been submitted in support of the registration of Mon-52249 Herbicide under EPA 524-ULU. These tests were considered supplementary data at the review of march 1992, and the review stated that the inhalation test could be upgraded if the data that was missing from the report could be submitted , but a new eye irritation study was necessary.

Monsanto had replied, in writing, presenting their point of view about both tests as well as supplying the missing data. The reply was studied prior to the meeting by PRS. The conclusions reached were presented at the meeting and some of the points discussed.

After the study of the supplied missing data, it was concluded that there really was not enough respirable particles to the test model to have a true effect at the alveolar level. What was being observed was the effect of the product at other areas where the particles were being deposited. The MMAD values did not reveal this, because normally half of the particles are expected to be under the MMAD value. With MMAD at 3.2, 2.2, and 3.0 , respectively for exposure groups I, II, and III, the respirable percentage of the particles would be expected to be adequate. This was not the case upon examination of the distribution. In fact less than five percent in the case of the highest and the lowest concentrations were truly respirable. Under 10 % of the middle level was respirable.

The decision to upgrade the data and accept it was made by considering:

1- The difficulty in generating the test atmosphere from such a viscous material

2- That a good effort was made to generate an acceptable test atmosphere

3- The toxicity of the test material, with the exception of eye irritation, was in category IV

The upgraded inhalation test is considered core minimum data in toxicity category III.

The eye study still has some areas that are not fully agreed upon by the representatives of the Registrant and PRS. Whether ulceration of the cornea is tantamount to opacity remained unresolved. PRS does acknowledge the possibility of small corneal ulcerations without stromal involvement. PRS contends that with three quarters of the corneal epithelium missing, the chances of

the base layer of the epithelium staying intact, with the absence of stromal involvement was pretty remote. This was based on the observation that the ulceration did not heal by day 7, as evidenced by staining. As the cornea heals downward from the epithelium into the stroma, the question " could a superficial ulceration of the corneal epithelium last this long without stromal involvement" was asked. This question is still unanswered. The participants of the meeting were not present at any of the observations; therefore all discussion is, in essence, theoretical. What remain are the results presented as recorded by the laboratory. These indicate that whatever the lesion was, it had healed sufficiently by day 10, so that the eye did not stain. The absence of staining at that interval does not necessarily mean that all has healed. PRS was concerned about the results primarily because the product contains a good percentage of surfactant. Surfactants are known to cause extensive eye damage. What was agreed upon was that the end result was the same.

Also discussed was the use of terminology used by the performing laboratory: the reported necrosis that disappeared within 24 hrs. Monsanto acknowledged that this was not proper. It was suggested that whatever is observed be reported as seen. Rather than calling the sloughing of the conjunctival epithelium necrosis, a superficial lesion could just be called sloughing. This would be sign of healing epithelium. As any kind of death of tissue is necrosis, the term used is not altogether incorrect, but suggests in depth injury which was not present in the conjunctiva.

PRS recommends the conservative grading of all observations. The eye, if the lesion is superficial, will heal without significantly changing the toxicity category even if small areas of dense opacity or ulceration are observed at the beginning of the test and graded with higher degrees of opacity. If the readings are done with adequate light and some magnification, as recommended by the guidelines, they will be accurate. It is recommended that the instruments and the source of light for evaluating the eyes be included in the report.

Upon reviewing all the data again, as well as the arguments presented by Monsanto, PRS has made the decision to upgrade the presented eye irritation study to core minimum data and accept it as support for the registration in toxicity category II.

It is stressed that a good description of what was done, the methodology, the instrumentation, and all of what was truly observed in any test is very valuable to the reviewer. Clear descriptions are most important in making correct decisions. Correct decisions, in turn, prevent the necessity of extensive correspondence, possible time consuming meetings, but above all delays in registration.

LABELING

The signal word is WARNING based on the eye irritation test.

The precautionary statement must include:

Causes substantial but temporary eye injury. Harmful if inhaled. Do not get in eyes or inhale dust or spray mist. Wear goggles, face shield or safety glasses. Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash before reuse.

The statement of practical treatment must include:

If in Eyes	Hold eyes open and flush with a steady gentle stream of water for 15 minutes. Get medical attention.
If swallowed	Drink promptly a large quantity of milk, egg white, or gelatin solution, or if these are not available large quantities of water. Avoid alcohol.
If inhaled	Remove victim to fresh air. If not breathing give artificial respiration, preferably mouth to mouth. Get medical attention

Tox Chem No 471AAB Current Date:5/14/92

Laboratories:Bio/Dynamics, Inc., Mettlers Road, East Millstone, NJ 08875-2360
Monsanto Company, Environmental Health Laboratory,
645 S.Newstead Ave., St. Louis, Missouri 63110

S T U D Y	M A T E R I A L	MRID No	R E S U L T S	TOX CAT	CORE GRADE
Oral Toxicity Limit test (rats) Bio/Dynamics 6053-91 8/15/91	MON-52249 Lot RUD-9104-3089-F	420355-02	LD_{50}>5000 mg/kg	IV	Guideline
Dermal Toxicity Limit Test (rats) Bio/Dynamics 6054-91 8/15/91	" " "	420355-03	LD_{50}>5000 mg/kg	IV	minimum
Inhalation Toxicity LD_{50} study (rats) Monsanto ML-91-136/EHL 91044 8/28/92	" " "	420355-04		III Upgraded 5/14/92	Minimum
Eye Irritation in Rabbits Bio/Dynamics 6023-91 8/15/92	" " "	420355-05		II Upgraded 5/14/92	Minimum
Dermal Irritation in Rabbits Bio/Dynamics 6055-91 8/15/91	" " "	420355-06	PII 0.8 minimally irritating	IV	Guideline
Dermal Sensitization in Guinea Pigs Bio/Dynamics	" "	420255-07	not sensitizer	NA	Guideline

524-454

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MEMORANDUM:

Subject: EPA File Symbol/EPA Reg. No.:524-ULU

From: Lucy D. Markarian, Biologist 4 3/11/92
Precautionary Review Section
Registration Support Branch
Registration Division (H7505C)

To: Robert J. Taylor/Vickie Walters, PM 25
Fungicide-Herbicide Branch
Registration Division (H7505C)

Thru: Thomas C. Ellwanger, Section Head E 3/26/92
Precautionary Review Section
Registration Support Branch
Registration Division (H7505C)

Applicant: Monsanto Agricultural Company
800 N. Lindbergh Blvd.
St. Louis, Missouri 63167

FORMULATION FROM LABEL:

Active Ingredient(s):	% by wt.
Glyphosate: N-(phosphonomethyl)glycine)	41.3 %
Inert Ingredient(s):	
.....	58.7 %
Total:	100.0 %

BACKGROUND

Monsanto Agricultural has submitted six studies for the registration of MON 52249 herbicide under EPA symbol 524-ULU.

RECOMMENDATION

The oral and dermal toxicity, dermal irritation and sensitization tests are acceptable support for the registration.
The inhalation toxicity is considered supplementary data until such time as the requested information as specified in the rationale for the rating of the test is supplied and found satisfactory.
The eye irritation study is considered supplementary data . A new eye study that evaluates eyes more realistically must be submitted.

The following is the rationale behind the rating of the submitted tests:

Dermal Toxicity- Core minimum

1-The test material was applied to a larger area than recommended in the guidelines. The guidelines state that the test material should be applied to 10 % of the body surface, not a minimum of 10 %. By shaving the entire trunk, dorsum and ventrum, the exposed area was significantly larger than it should have been. This minimizes the effects on the skin consequently alters the rate of absorption.

2- Individual doses for rats is not presented. This would have given a better idea of the propriety of the area used.

3- the guidelines state that the test material should be applied to the dorsum of the animals. In the test all the shaved area, including the ventrum, was used.

Inhalation Toxicity- supplementary: upgradeable

1-MMAD was calculated only once during exposure. There is no assurance that the particle size remained constant during the entire exposure.

2- The particle size distribution is not presented. There are large differences in the exposure concentrations. Of greater concern is the difference in concentration between group 2 and 1. Group 2 was exposed to 1.3 mg/L and group 1 was exposed to 5.8 mg/L. In group 1 the mortality rate was twice that of group 2 . Since the particle size distribution is not presented, it is not possible to determine if less than expected mortality in group 1 was due to a lower percentage of respirable particles. Giving the percentage of particles under 1 um is not enough.

3-The system of generation of the test atmosphere was

different at the highest level. PRS would prefer to have all levels of exposure to be generated the same way. This would avoid adding a variable to the test system. The presentation of the particle size distribution would have been reassuring, especially if the distribution at both exposures were comparable in percentage at comparable stages.

4-The summary table of observed symptoms of toxicity must agree with the tabulated data for individual observations. This was not the case in the presented data. It is not certain what symptoms were observed in which group. Group 1 and group 3 seem to be confused with one another according the way it is presented in the report.This needs to be clarified.

5- The sampling rates and volumes must be specific. It is not sufficient to state that it was sampled at a known rate. The volumes of sampling must be uniform. It is not explained why the volume varied from 5 to 30 L.

6- It is not clear how opacity of the eye observed at death can be attributable to death. A clarification of this as well as what is meant by other terminology as :"disuse of limbs", and "High pitched sounds" is necessary. Was the "disuse" paralysis, and neurological in origin or was it physical injury? Were the high pitched sounds due to respiratory distress or distress in general?

The test may be upgraded if the particle size distribution is presented and data clarified as mentioned in the above remarks.

Eye Irritation- Supplementary

1-The grading of the ocular irritation, contrary to what the laboratory believes to be according to EPA grading system, is not according to the grading system the guidelines have specified. There is no EPA grading system. EPA guidelines have adopted the Draize system in its entirety.

2-Draize makes no distinction between ulceration and opacity. Therefore, PRS expects all ulceration and necrosis to be graded with the maximum irritation score of opacity. If the corneal epithelium is missing due to treatment, as it is defined in the legend, then this is destruction of tissue. If evaluated correctly, it is not easily reversible, and certainly not within 4 days.

3-In recording iritis, if it is present at all it is remarkable, no matter how slight the observer considers it to be, and must be given a numerical evaluation. If it is slight enough, the observed iritis will not be persistent, and will not influence the toxicological standing of the test.

4-Necrosis of the conjunctiva is considered in depth injury.

PRS is unable to accept necrosis that is present one day and disappears the next without leaving a trace, as it is recorded in two cases, and in another healed completely within four days. Necrosis is defined as death of tissue, either as individual cells, groups of cells, or in small localized areas. The recorded necrosis would have to be in localized areas to be observed grossly, since individual cells and even small groups of cells would not be observable to the naked eye. It is not clear how a group of cells could die and be replaced overnight with others, without a trace of the destruction.

A new eye irritation test must be submitted that evaluates the eyes more realistically.

LABELING

It is not possible to assign a signal word at this time due to the supplementary rating of the eye study.

Upon the presentation of a successful eye study, and supplying the missing information from the inhalation test,precautionary label will be reviewed. The successful tests at this time do not require any precautionary statements.

E 8.

DATA REVIEW FOR ACUTE ORAL TOXICITY TESTING (§ 81-1)

Product Manager:25
MRID No.:420355-02
Testing Facility: Bio/Dynamics, Inc.
Author(s): Donna L. Blaszcak
Species: Rat, Spragur Dawley
Age:9 - 12 weeks old
Weight: Males 261-284 g, Females 226-252 g
Source: Charles River Breeding Laboratories,Kingston, NY
Test Material:MON-52249 Lot RUD-9104-3089-F, yellow liquid
Quality Assurance (40 CFR §160.12): Included

Reviewer: L. Markarian
Report Date:2/11/92
Report No.6053-91

Conclusion:

1. **The estimated LD_{50} is** > 5000 mg/kg
2. **Tox. Category:** IV **Classification:** Guideline

Procedure (Deviations from §81-1):

Fasted animals were intubated with the test material as received. Observations were at 1, 2, and 4 hrs after intubation, and daily thereafter. Body weights were taken before fasting, at initiation and on days 7 and 14 and at death. Necropsy was performed on all animals. Carbon dioxide euthanasia was used.

Results:

Dosage mg/kg	(Number Killed/Number Tested)		
	Males	Females	Combined
5000	0/5	1/5	1/10

Symptoms & Gross Necropsy Findings:
One female died on day 2. Symptoms of toxicity included dyspnea, wet and dry rales, soft stools and resulting stains, unthrifty appearance, abdominal gripe, decreased activity and decreased food consumption.
Dry rales, unthrifty appearance, and decreased food consumption lasted to termination in one animal. One male lost body weight at 7 days, and although gained back some of the weight, did not reach the pretest body weight at termination.
At necropsy the female that died showed a swollen uterus and red walls of the intestines as well as some autolytic changes. The survivors showed discoloration of and red foci on the lungs.

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DATA REVIEW FOR ACUTE DERMAL TOXICITY TESTING (§81-2)

Product Manager:25
MRID No.: 420355-03
Testing Laboratory: Bio/ Dynamics
Author(s): Donna L. Blaszcak
Species: Rat, Sprague Dawley
Weight:males 253 - 269 g, females 241 - 266 g
Source: Charles River Breeding Laboratories, Inc. Kingston, NY
Test Material:MON 52249, Lot RUD-9104-3089-F, yellow liquid
Quality Assurance (40 CFR §160.12): Included

Reviewer: L. Markarian
Report Date:3/11/92
Report No.:6054-91

Summary:

1. **The estimated LD_{50} is > 5000 mg/kg**

2. **Tox. Category:** IV **Classification:** core minimum

Procedure (Deviation From §81-2):

The trunks of the rats were clipped 24 hr prior to application. The test material was applied to the entire shaved area of the animals, covered with 8 ply gauze and overwrapped with plastic secured by tape. At 24 hours the wrappings were removed and the test sites wiped with wet paper towels. Observations were at 1, 2, and 4 hours after application and daily thereafter. There were twice daily viability checks. Necropsy was performed on all animals. Carbon dioxide euthanasia was used.

Results:

Reported Mortality

DOSAGE mg/kg	(NUMBER KILLED/NUMBER TESTED)		
	Males	Females	Combined
5000	0/5	0/5	0/10

Symptoms & Gross Necropsy Findings:

No mortality, signs of systemic toxicity or gross pathology is reported. It is stated that no severe dermal reactions were observed.

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DATA REVIEW FOR ACUTE INHALATION TOXICITY TESTING (§81-3)

Product Manager:25 **Reviewer:** L. Markarian
MRID No.: 420355-04 **Report Date:**3/11/92
Testing Laboratory: Monsanto Environmental Health Laboratory **Report No.:**ML-91-136/ EHL 91044
Author(s):B.R.Dudek
Species: Rat, Sprague Dawley
Weight:Males 292-325 g, Females 209 - 228 g
Source: Charles River Breeding Laboratory, Portage, MI
Test Material:MON 52249, Lot RUD-9104-3089-F, Yellow liquid
Quality Assurance (40 CFR §160.12): Included

Summary:

1. LC_{50} (mg/kg): **Males** =1.6 (0.33728-8.2727)
   Females = 2.8 (0.56359-26.410)
   Combined =2.1 (1.0137-4.6700)
2. **Tox. Category:** III **Classification:** supplementary upgradeable

Procedure (Deviation From §81-3):

Four hour exposures were in 250 L NY University style stainless steel chamber.

Two types of generation were used. For the two lower chamber concentrations (group II & III) the double flask/Laskin type nebulizer and discriminator system, and at the highest concentration (Group I) the FMI pump/ nebulizer system was used to create the aerosol.
The double flask system created a finer aerosol, but was not able to create a high enough concentration to determine the LC_{50} of the test material. Each flask contained a nebulizer. The generated vapor passed through a particle discriminator before entering the exposure chamber,as a result the smaller particle size was possible. The discriminator was designed at Monsanto.
The pump/ nebulizer system consisted of FMI fluid metering pump(Model RP-G20) that delivered the test fluid to the liquid inlet of the nebulizer. The aerosol was generated by compressed dried air delivered to the nebulizer. The resultant atmosphere was introduced into the chamber.

Chamber concentrations were measured four times during each exposure by sampling from the breathing zone with glass impingers containing 0.1 % Antifoam in water at a known rate (unspecified) in 5- 30 L volume. It is not stated why such variation was necessary in the sampling volume. Analysis was by liquid chromatography.

Particle size analysis was made using an Anderson Cascade Impactor once every exposure at the sampling rate of 28 lpm. Volume of sample not specified.

Chamber air flow, temperature and humidity were monitored constantly and recorded at 30 minute intervals.

Observations were hourly during exposure but limited by the placement of the cages in the chamber. The animals were observed immediately after the removal from the chamber and daily thereafter. There were mortality checks twice a day.
Body weights were recorded at initiation and on days 2, 7, and 14.
Necropsy was performed on all animals.

RESULTS

Group	**III**	**II**	**I**
Mean Concentration mg/L analytic	0.25	1.3	5.8
Range	**0.24-0.28**	**1.1-1.5**	**5.5-6.0**
MMAD um	3.0	2.2	3.2
GSD	1.7	1.7	1.8
Particles< 1 um %	3.9	7.6	3.0
Mean air flow lpm	146.4	128.6	102.2
Mean temperature ° C	23.3	23.2	23.6
Mean Humidity %	49.9	54.2	73.9
MORTALITY			
Males	0/5	3/5	4/5
Females	0/5	1/5	4/5
combined	0/10	4/10	8/10

Symptoms and Gross Necropsy Findings:

The symptoms of toxicity are reported as dehydration, disuse of limbs (paralysis?), labored ,rapid or shallow respiration, high pitched sounds, rattling sounds (not clear if respiratory) nasal discharge, periocular encrustation, partially or completely closed eyes, focal or general loss of hair, and ocular opacity. These symptoms are given as summaries and as individual observations. However the individual observations do not agree with the summary tables. What is attributed to group 3 in individual observations is attributed to group 1 in the summary.
Necropsy statement says that opacity observed in the eyes of the highest level animals were attributable to death. Other observations at necropsy as abnormal discharge and encrustation from the nose and the turbinates were not considered to be exposure related either.

3/12

DATA REVIEW FOR ACUTE EYE IRRITATION TESTING (§81-4)

Product Manager:25
MRID No.:420355-05
Testing Laboratory: Bio/Dynamics, Inc.
Author(s): Donna C. Blaszcak
Species: Rabbit, New Zealand White
Sex: 3 male and 3 female
Weight:2.2 - 2.7 K
Source: Hazleton Research Products, Inc., Denver, PA
Dosage:0.1 ml
Test Material:MON 52249, Lot RUD-9102-2825-F, yellow liquid
Quality Assurance (40 CFR §160.12): Included

Reviewer: L. Markarian
Report Date:3/11/92
Report No.:6023-91

Summary:

1. **Toxicity Category:**

2. **Classification:**Supplementary

Procedure (Deviations From §81-4):

Test material as received was instilled in the conjunctival sacs of six preexamined right eyes. Left eyes served as control. examinations were conducted at 1, 24, 48, 72 hours and on days 7, 10, and 14, or until all irritation cleared. Scoring was according to a method similar to Draize. There were twice daily viability checks.

Results:

Observations	(number "positive"/number tested)							
	Hour	Days						
	1	1	2	3	4	7	14	21
Cornea Opacity	0/6	1/6[1]	2/6[2]	1/6	-	1/6[1]	0/6	
Iris	1/6[3]	0/6	0/6	0/6	-	0/6	0/6	
Conjunctivae								
Redness	6/6	6/6	6/6	5/6	-	2/6	0/6	
Chemosis	6/6	3/6	0/6	0/6	-	0/6	0/6	
Discharge	5/6	0/6	0/6	0/6	-	0/6	0/6	
Necrosis	0/6	0/6	2/6	1/6	-	0/6	0/6	

-1 The draize evaluation system which EPA uses does not distinguish between ulceration and opacity. Ulceration must be graded as opacity. Ulceration should be graded with grade 4 opacity, as it is described as "absence of a gross patch of corneal epithelium", and this is considered equivalent to irreversible damage.

A3

-2 Dullness observed after the one hour reading cannot be evaluated as a negative response. Grading with + signs is not included in the accepted Draize Scale.
-3 If iritis is present at all it must be evaluated with a numerical grade of 1. As it is stated for grading of opacity, + signs are not acceptable according to the Draize scoring system.

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DATA REVIEW FOR SKIN IRRITATION TESTING (§81-5)

Product Manager:25
MRID No.: 420355-06
Testing Laboratory: Bio/Dynamics Inc.
Author(s): Donna C. Blaszcak
Species: Rabbit, New Zealand White
Age:at least 8 weeks old, Young adult
Sex:two males & four females
Dosage:0.5 ml
Test Material:MON 52249,Lot RUD-9104-3089-F, Yellow liquid
Quality Assurance (40 CFR §160.12): Included

Reviewer: L. Markarian
Report Date:3/11/92
Report No.:6055-91

Summary:

1. **The Primary Irritation Index** =0.8
2. **Toxicity Category:**IV
3. **Classification:**Guideline

Procedure (Deviations From §81-5):

Undiluted test material was applied to the shaved skin of the animals at two locations on the dorsum contralaterally. The sites were covered with 1 x 1 inch gauze and tape.the trunks of the animals were wrapped in gauze and covered with porous tape to semiocclude the sites. Collars were placed around the necks of the animals. At 4 hrs the wrappings were removed and the sites wiped with wet paper towels. Observations were made at 30 min, and 24, 48, and 72 hrs according to a scale similar to Draize.

Results:

Grade 2 erythema was observed at 30 minutes at 10/12 sites. One of these also showed grade 1 edema. At later intervals the highest irritation was grade 1 erythema. One animal still showed grade 1 erythema at 72 hrs.

Special Comments:

Guidelines do not require more than one patch per test material. Using more than one patch per animal is not encouraged.

1-5

DATA REVIEW FOR SKIN SENSITIZATION TESTING (§81-6)

Product Manager:25
MRID No.: 420355-07
Testing Laboratory: Bio/Dynamics, Inc.
Author(s): Donna L. Blaszcak
Species: Guinea Pig, Hartley
Weight:307 - 419 g
Source: Hazleton Research Products, Inc.
Test Material: Mon 52249, Lot RUD-9104-3089-F, Yellow Liquid
Positive Control Material:DNCB
Quality Assurance (40 CFR §160.12): Included

Reviewer: L. Markarian
Report Date:3/11/92
Report No.:6056-91

Method: Closed Patch Repeat Insult Dermal Sensitization (Buehler)

Summary:

1. **This Product is not a dermal sensitizer.**

2. **Classification:**Guideline

Procedure (Deviation From §81-6):

A pretest screening was made to define the induction and elicitation concentrations, using six guinea pigs and four concentrations. Four patches were applied per guinea pig: one each at 100 % and dilutions at 50, 25, and 10 % in distilled water in Hilltop chambers. No reaction was observed at any concentration, and 100 % was used for inductions and elicitations.

The test material was applied to the shaved skin of ten animals, undiluted, in 0.3 ml aliquots in Hilltop chambers. The trunks of the animals were wrapped in impermeable plastic and firmly secured by elastic bandage wrapped around the trunk also. At six hours the wrappings were removed and the sites wiped clean of residue with gauze and water. The procedure was repeated three times, once per week for three weeks. Challenge was two weeks after the last induction at the same concentration and applied similarly at a naive site. At the same time ten naive animals were challenged similarly.
Evaluations were made at 24 and 48 hours after each induction and challenge applications according to Buehler.

Reference is given to a series of tests conducted with DNCB (induced at 0,5 % and challenged at 0,3 %), the last of which was within three months of the presented test. DNCB tests demonstrate the ability of the laboratory to induce sensitization.

Results:

No reaction was observed after any of the applications at induction or at challenge. The test material is not considered to be a sensitizer.

Tox Chem No 471AAB Current Date:3/11/92

Laboratories:Bio/Dynamics, Inc., Mettlers Road, East Millstone, NJ 08875-2360
Monsanto Company, Environmental Health Laboratory,
645 S.Newstead Ave., St. Louis, Missouri 63110

STUDY	MATERIAL	MRID No	RESULTS	TOX CAT	CORE GRADE
Oral Toxicity Limit test (rats) Bio/Dynamics 6053-91 8/15/91	MON-52249 Lot RUD-9104-3089-F	420355-02	LD_{50}>5000 mg/kg	IV	Guideline
Dermal Toxicity Limit Test (rats) Bio/Dynamics 6054-91 8/15/91	" " "	420355-03	LD_{50}>5000 mg/kg	IV	minimum
Inhalation Toxicity LD_{50} study (rats) Monsanto ML-91-136/EHL 91044 8/28/92	" " "	420355-04			Supplementary Upgradeable
Eye Irritation in Rabbits Bio/Dynamics 6023-91 8/15/92	" " "	420355-05			Supplementary
Dermal Irritation in Rabbits Bio/Dynamics 6055-91 8/15/91	" " "	420355-06	PII 0.8 minimally irritating	IV	Guideline
Dermal Sensitization in Guinea Pigs Bio/Dynamics 6056-91 9/9/91	" "	420255-07	not sensitizer	NA	Guideline

SCREEN OK

DP BARCODE: D209471

CASE: 016767 DATA PACKAGE RECORD DATE: 11/17/94
SUBMISSION: S475334 BEAN SHEET Page 1 of 1

* * * CASE/SUBMISSION INFORMATION * * *

CASE TYPE: REGISTRATION ACTION: 674 8 MNTH RESP-PROD SPC DATA
CHEMICALS: 103601 Glyphosate, isopropylamine salt 41.0000%

ID#: 000524-00339 SHACKLE C HERBICIDE BY MONSANTO
COMPANY: 000524 MONSANTO AGRICULTURAL CO
PRODUCT MANAGER: 25 ROBERT TAYLOR 703-305-6800 ROOM: CM2 241
PM TEAM REVIEWER: EMILY MITCHELL 703-308-8583 ROOM: CS1 1L3
RECEIVED DATE: 10/13/94 DUE OUT DATE: 04/11/95

* * * DATA PACKAGE INFORMATION * * *

DP BARCODE: 209471 EXPEDITE: N DATE SENT: 11/17/94 DATE RET.: / /
CHEMICAL: 103601 Glyphosate, isopropylamine salt
DP TYPE: 001 Submission Related Data Package
CSF: Y LABEL: Y

ASSIGNED TO	DATE IN	DATE OUT
DIV : RD	/ /	/ /
BRAN: RSB	/ /	/ /
SECT:	/ /	/ /
REVR :	/ /	/ /
CONTR:	/ /	/ /

ADMIN DUE DATE: 02/15/95
NEGOT DATE: / /
PROJ DATE: / /

* * * DATA REVIEW INSTRUCTIONS * * *

ATTN: Tina Levine
Please review 8 month response for acute toxicity studies.
This product is identical to Monsanto's Roundup Export
Herbicide Reg. #524-308.

* * * DATA PACKAGE EVALUATION * * *

No evaluation is written for this data package

* * * ADDITIONAL DATA PACKAGES FOR THIS SUBMISSION * * *

DP BC	BRANCH/SECTION	DATE OUT	DUE BACK	INS	CSF	LABEL
209426	RSB	11/16/94	02/14/95	Y	Y	Y

DATE OUT: APR 24 1995

SUBJECT: PRODUCT CHEMISTRY REVIEW OF: MP [ ] EP [X]
DP BARCODE No.: 209426 REG./File Symbol No.: 524-339
PRODUCT NAME: Shackle Herbicide by Monsanto, 41% AI

TO: 25 Robert Taylor/Emily Mitchell
Fungicide-Herbicide Branch
Registration Division (H7505C)

FROM: Sami Malak, Chemist Sami Malak
Product Chemistry Review Section
Registration Support Branch/RD (H7505W)

THRU: Harold Podall, Section Head HP 4/25/95
Product Chemistry Review Section

SUMMARY OF FINDINGS:

1. A Reregistration Eligibility Document (RED) for Glyphosate, Case #0178, was published during September, 1993. Generic data requirements was determined to be substantially complete.

2. This end-use product, Shackle Herbicide by Monsanto, Reg. No. 524-339, is similar to Monsanto's Roundup Export Herbicide, Reg. No. 524-308. Product chemistry data for Reg. No. 524-308 was previously submitted and found adequate in support of the reregistration requirements (D #209406, S. Malak, 12/20/ 94).

3. The submitted label for this end-use product, Shackle Herbicide by Monsanto, Reg. No. 524-339, EPA received 10/13/94, is acceptable.

4. The submitted CSF for this end-use product, Shackle Herbicide by Monsanto, Reg. No. 524-339, EPA received 10/13/94, dated 7/16/80, is unacceptable: The CSF should indicate the upper and lower certified limits of the ingredients.

RECOMMENDATIONS:

After resolving Finding 4 above, we recommend for reregistration of this end-use product, Shackle Herbicide by Monsanto, Reg. No. 524-339.

H7505W:RD:RSB:PCRS:CS-1:Rm650:Sami Malak:s.m.:04/24/95:703-308-8392:524-339.

DP BARCODE: D209426

CASE: 01676[illegible] DATA PACKAGE RECORD DATE: 11/16/94
SUBMISSION: S47533[illegible] BEAN SHEET Page 1 of 1

* * * CASE/SUBMISSION INFORMATION * * *

CASE TYPE: REGISTRATION ACTION: 674 8 MNTH RESP-PROD SPC DATA
CHEMICALS: 103601 Glyphosate, isopropylamine salt 41.0000%

ID#: 000524-00339 SHACKLE C HERBICIDE BY MONSANTO
COMPANY: 000524 MONSANTO AGRICULTURAL CO
PRODUCT MANAGER: 25 ROBERT TAYLOR 703-305-6800 ROOM: CM2 241
PM TEAM REVIEWER: EMILY MITCHELL 703-308-8583 ROOM: CS1 1L3
RECEIVED DATE: 10/13/94 DUE OUT DATE: 04/11/95

* * * DATA PACKAGE INFORMATION * * *

DP BARCODE: 209426 EXPEDITE: N DATE SENT: 11/16/94 DATE RET.: / /
CHEMICAL: 103601 Glyphosate, isopropylamine salt
DP TYPE: 001 Submission Related Data Package
CSF: Y LABEL: Y

ASSIGNED TO	DATE IN	DATE OUT	ADMIN DUE DATE: 02/14/95
DIV : RD	/ /	/ /	NEGOT DATE: / /
BRAN: RSB	/ /	/ /	PROJ DATE: / /
SECT:	/ /	/ /	
REVR :	/ /	/ /	
CONTR:	/ /	/ /	

* * * DATA REVIEW INSTRUCTIONS * * *

Please review 8 month response for product chemistry.
This product is identical to Monsanto's Roundup Export
Herbicide Reg. #524-308.

* * * DATA PACKAGE EVALUATION * * *

No evaluation is written for this data package

* * * ADDITIONAL DATA PACKAGES FOR THIS SUBMISSION * * *

DP BC	BRANCH/SECTION	DATE OUT	DUE BACK	INS	CSF	LABEL

Monsanto

Monsanto Company
Suite 1100
700 14th Street, N.W.
Washington, D.C. 20005

October 10, 1994

Document Processing Desk (RED-RD-PM25)
Office of Pesticide Programs (H7504C)
U.S. Environmental Protection Agency
Room 226A, Crystal Mall 2
1921 Jefferson Davis Highway
Arlington, Virginia 22202

Attention: Mr. Robert J. Taylor
Product Manager (25)

Subject: **Shackle® C Herbicide (EPA Reg. No. 524-339)**
Exchange® Herbicide (EPA Reg. No. 524-339)
Submission of Product-Specific Data and Labeling
Glyphosate Reregistration Eligibility Decision (RED)

Dear Sir:

As required by the Glyphosate Reregistration Eligibility Decision (RED) document, Monsanto is enclosing the following product-specific information on Shackle® C Herbicide and Exchange® Herbicide (EPA Reg. No. 524-339):

- Application for Reregistration (EPA Form 8570-1)
- Five (5) copies of the Labeling (see below)
- Product-Specific Data (see below)
- Two (2) copies of the Confidential Statement of Formula
- Certification with Respect to Citation of Data (EPA Form 8570-31)

These manufacturing use products are identical to Roundup® Export Herbicide (EPA 524-308); please refer to the product-specific data submitted under EPA Reg. No. 524-308 to support the products registered under EPA Reg. No. 524-339.

TELEPHONE (202) 783-2460 FACSIMILE (202) 783-2468

Five (5) copies of the following labels are also enclosed:

- Shackle® C Herbicide 54 Gallon Container Label (MAP-2233.12/53L)
- Shackle® C Herbicide Bulk Container Label (MAP-2233.13/53L)
- Exchange® Herbicide 54 Gallon Container Label (MAP-2975.01/53L)
- Exchange® Herbicide Bulk Container Label (MAP-3207.01/53L)

If you have any questions regarding this submission, please contact Russ Schneider or me.

Sincerely,

Sheila A. Schuette

Sheila A. Schuette, Ph.D.
Manager, Regulatory Affairs
(314) 694-7248

cc: R.P. Schneider
L.A. Suba
K.A. Buteau

Please read instructions on reverse before completing form. Form Approved. OMB No. 2070-0060. Approval expires 2-28-95

EPA

United States
Environmental Protection Agency
Washington, DC 20460

[ ] Registration
[ ] Amendment
[x] Other

OPP Identifier Number: 219272

Application for Pesticide - Section I

1. Company/Product Number: 524-339	2. EPA Product Manager: Robert J. Taylor	3. Proposed Classification: [x] None [ ] Restricted
4. Company/Product (Name): Shackle® C Herbicide Exchange® Herbicide	PM#: 25	
5. Name and Address of Applicant *(Include ZIP Code)*: Monsanto Company, 700 14th Street, N.W., Suite 1100, Washington, DC 20005 [ ] *Check if this is a new address*	6. **Expedited Reveiw.** In accordance with FIFRA Section 3(c)(3)(b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____	

Section - II

[ ] Amendment - Explain below.
[ ] Resubmission in response to Agency letter dated _____
[ ] Notification - Explain below.
[ ] Final printed labels in repsonse to Agency letter dated _____
[ ] "Me Too" Application.
[x] Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

Application for Reregistration

Section - III

1. Material This Product Will Be Packaged In:

Child-Resistant Packaging	Unit Packaging	Water Soluble Packaging	2. Type of Container
[ ] Yes [x] No	[ ] Yes [x] No	[ ] Yes [x] No	[ ] Metal [x] Plastic [ ] Glass [ ] Paper [ ] Other (Specify)
* ***Certification must be submitted***	If "Yes" Unit Packaging wgt. / No. per container	If "Yes" Package wgt / No. per container	

3. Location of Net Contents Information	4. Size(s) Retail Container	5. Location of Label Directions
[ ] Label [x] Container	54 gal; bulk	[x] On label

6. Manner in Which Label is Affixed to Product: [ ] Lithograph [ ] Paper glued [ ] Stenciled [x] Other vinyl glued

Section - IV

1. Contact Point *(Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)*

Name	Title	Telephone No. (Include Area Code)
Dr. Russell P. Schneider	Agricultural Regulation Director	(202) 783-2460

Certification

I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowlingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

2. Signature	3. Title	6. Date Application Received (Stamped)
Sheila A. Schuette	Manager, Regulatory Affairs	
4. Typed Name: Sheila A. Schuette, Ph.D.	5. Date: October 10, 1994 10/10/94	

EPA Form 8570-1 (Rev. 3-94) Previous editions are obsolete. White - EPA File Copy (original) Yellow - Applicant Copy

PAPERWORK REDUCTION ACT NOTICE and INSTRUCTIONS

PAPERWORK REDUCTION ACT NOTICE: Public reporting burden for this collection of information is estimated to average 0.85 hour per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to Chief, Information Policy Branch, PM-223, U.S. Environmental Protection Agency, 401 M Street, SW, Washington, DC 20460; and to the Office of Information and Regulatory Affairs, Office of Management and Budget, Washington, DC 20503.

INSTRUCTIONS: This form is to be used for all applications for new registration, end use reregistration, amendment, resubmission, to applications for notifications, final printed labeling, reregistration, etc. In order to process an application for a new registration submitted on this form, the following material must accompany the application:

1. Certification with Respect to Citation of Data (EPA Form 8570-29). [If not exempted by 40 CFR 152.81 (b) (4)];
2. Confidential Statement of Formula (EPA Form 8570-4);
3. Formulator's Exemption Statement (EPA Form 8570-27);
4. Five copies of draft labeling;
5. Three copies of any data submitted;
6. Authorization letter where applicable;
7. Matrices where applicable.

Submission of Labeling - Labeling should first be submitted in the form of draft labels with all applications for new registration. Such draft labels may be in the form of typed label text on 8.5 x 11 inch paper or a mockup of the proposed label. If prepared as a mockup, it should be constructed in such a way as to facilitate storage in an 8.5 x 11 inch file. Mockup labels significantly smaller than 8.5 x 11 inches should be mounted on 8.5 x 11 inch paper for submission.
Submission of Data - Data submitted in support of this application must be submitted in accordance with PR Notice 86-5.

SPECIFIC INSTRUCTIONS: Please read the instructions listed below before completing this application. First determine the type of registration action, listed in Block A, for which you are submitting this application. For applications submitted in connection with New Registration actions, Sections I, III, and IV must be completed by the applicant. For applications submitted in connection with amended registration actions, resubmissions, notifications, reregistrations, etc., Sections I, II, and IV must be completed by the applicant.
Block A - Check the appropriate action for which you are submitting this form.

SECTION I - This section must be completed, as applicable, for all registration actions.

1. Company/Product Number - Insert your Company Number, if one has been assigned by EPA. This number may have been assigned to you as a basic registrant, a distributor, or as an establishment. If your product is registered, insert the Product Number.
2. EPA Product Manager - If known, fill in the name and PM number of the EPA Product Manager.
3. Proposed Classification - Specify the proposed classification of this product.
4. Product Name - Enter the complete product name of this pesticide as it will appear on the label. The name must be specific to this product only. Duplication of names is not permitted among products of the same company. Do not include any brand name or company line designations.
5. Name and Address of Applicant - The name of the firm or person and address shown in your application is the person or firm to whom the registration will be issued. If you are acting in behalf of another party, you must submit authorization from that party to act for them in registration matters. An applicant not residing in the United States must have an authorized agent residing in the United States to act for them in all registration matters. The name and complete mailing address of such an agent must accompany this application.
6. Expedited Review - FIFRA section 3 (c) 3 (B) provides for expedited review of applications for registration, or amendments to existing registrations, that are similar or identical to other pesticide products that are currently registered with the EPA. In order for your application to be eligible for expedited review, you must provide us with the EPA Registration Number and product name of the product you believe is similar to or identical to your product. The product must be similar or identical in both formulation and labeled uses.

SECTION II - This section must be completed for all applications submitted to amend the registration only of a currently registered product (Amendment), for a resubmission in response to an Agency letter, for notifications to the Agency, for the submission of final printed labeling, for reregistration and for any other action that pertains to a specific EPA-registered product. This section is not to be used for a new application for registration.

1. Subject of submission - Check the applicable block and provide the Agency letter date if appropriate. Provide a brief explanation of the purpose(s) for the submission, such as "the addition of a site, pest or crop (specify)"; "amend the Confidential Statement of Formula by..."; "reregistration submission"; general label revision of use directions." Attach a separate page if additional space is needed.

SECTION III. (Packaging and Container Information) - This Section must be completed for all applications submitted in connection with new registration or applicable amendments.

1. Type of Packaging - Check the appropriate block if your product will be packaged in the indicated packaging types. Indicate the size of the individual packets and number per retail container.
2. Type of Retail Container - Indicate type of container in which product will be marketed.
3. Location of Net Contents - Specify the net contents of all retail containers for your product.
4. Size(s) of Retail Container - Specify the net contents of all retail containers for your product.
5. Location of Use Directions - Indicate the location of the use directions for your product.
6. Manner in which label is affixed to product - Indicate the method product label is attached to retail container.

SECTION IV. (Contact Point) - This Section must be completed for all applications for Registration actions, i.e., new products registration, resubmission, "me-too," reregistration, etc.

1-5. Self-explanatory.
6. EPA Use Only.

United States Environmental Protection Agency
Washington, DC 20460

EPA Certification with Respect to Citation of Data

Form Approved
OMB No. 2070-0060
Approval Expires 11-30-93

Applicants Name and Address	EPA File Symbol/Registration Number
Monsanto Company 700 14th Street, N.W., Suite 1100 Washington, DC 20005	524-339
	Product Name: Shackle® C Herbicide Exchange® Herbicide
	Date of Application: October 10, 1994

NOTE: If your product is a 100% repackaging of another EPA-registered product that you purchase, and is labeled for the same uses, you do not need to submit this form. You must submit the Formulator's Exemption Statement (EPA Form 8570-27).

1. This application is supported by all data submitted or cited in the application. In addition, if cite-all options are indicated, this application is supported by all data in the Agency's files that concern the properties or effects of this product that is identical or substantially similar, and that is one of the types of data that would be required to be submitted if this application sought the initial registration of a product of identical or similar composition and intended uses under the data requirements in effect on the date of apropval of this application. (Check the appropriate boxes, in items 2 and 3 below, that pertain to your application.)

2. I certify that, for each study cited in support of this application for registration that is an exclusive use study,

   |x| I am the original submitter*; or

   | | I have obtained the written permission of the original data submitter to cite that study*

3. I certify that, for each study cited in support of this application for registration that is not an exclusive use study:

   a. |x| I am the original data submitter*; or

      | | I have obtained the written permission of the original data submitter to cite that study*; or

   b. | | I have notified in writing the companies that have submitted data I have cited to support this application and have offered to: (a) Pay compensation for those data in accordance with section 3(c)(1)(D) and 3(c)(2)(D) of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA); and (b) Commence negotiations to determine which data are subject to the compensation requirement of FIFRA and the amount and terms of compensation due, if any. The companies I have notified are: (Check one)

      | | All companies listed on the Pesticide Data Submitters List for all active ingredients contained in my product (cite-all method or cite-all option under Selective Method*). (Also, sign the General Offer Statement below.)

      | | Those companies that have submitted the studies which I have cited (Selective method*).

   * A Data Matrix identifying these studies is attached. (Note: a Data Matrix is not required under the cite-all method.)

Signature	Name and Title	Date
Sheila A. Schuette	Sheila A. Schuette, Ph.D. Manager, Regulatory Affairs	October 10, 1994

General Offer to Pay: I hereby offer and agree to pay compensation to other persons, with regard to the approval of this application, to the extent required.

Signature	Name and Title	Date

EXCHANGE™

HERBICIDE BY Monsanto

Read the entire label before using this product.

Read "LIMIT OF WARRANTY AND LIABILITY" before buying or using. If terms are not acceptable, return at once unopened.

PRECAUTIONARY STATEMENTS

Hazards to Humans and Domestic Animals

Keep out of reach of children.

DANGER!

CAUSES IRREVERSIBLE EYE DAMAGE.
HARMFUL IF SWALLOWED OR INHALED.
MAY CAUSE SKIN IRRITATION.
Do not get in eyes, on skin or on clothing.
Wear goggles or face shield.
Avoid breathing vapor or spray mist.
Wash thoroughly with soap and water after handling.
Remove contaminated clothing and wash before reuse.

FIRST AID: IF IN EYES, immediately flush with plenty of water for at least 15 minutes. Get medical attention.

IF ON SKIN, immediately flush with plenty of water. Remove contaminated clothing. Wash clothing before reuse.

IF SWALLOWED, this product will cause gastrointestinal tract irritation. Immediately dilute by swallowing water or milk. Get medical attention.

NOTE TO PHYSICIAN: Probable mucosal damage may contraindicate the use of gastric lavage.

IF INHALED, remove individual to fresh air. Get medical attention if breathing difficulty develops.

In case of an emergency involving this product, Call Collect, day or night (314) 694-4000.

Environmental Hazards

Do not apply directly to water, to areas where surface water is present or to intertidal areas below the mean high water mark. Do not contaminate water when disposing of equipment washwaters.

Physical or Chemical Hazards

Solutions of this product should be mixed and stored using only stainless steel, aluminum, fiberglass, plastic or plastic-lined steel containers.

DO NOT MIX OR STORE THIS PRODUCT OR SOLUTIONS OF THIS PRODUCT IN GALVANIZED STEEL OR UNLINED STEEL (EXCEPT STAINLESS STEEL) CONTAINERS OR SPRAY TANKS.

This product or solutions of this product react with such containers and tanks to produce hydrogen gas which may form a highly combustible gas mixture. This gas mixture could flash or explode, causing serious personal injury, if ignited by open flame, spark, welder's torch, lighted cigarette or other ignition source.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in any manner inconsistent with its labeling.

Storage and Disposal

Do not contaminate water, foodstuffs, feed or seed by storage of disposal.

DISPOSAL:
Wastes resulting from the use of this product that cannot be used or chemically reprocessed should be disposed of in a landfill approved for pesticide disposal or in accordance with applicable Federal, state or local procedures.

Emptied container retains vapor and product residue. Observe all labeled safeguards until container is cleaned, reconditioned or destroyed. DO NOT CUT OR WELD ON OR NEAR THIS CONTAINER.

Triple rinse emptied bulk containers. Then offer for recycling or reconditioning, or dispose of in a manner approved by state and local authorities.

FOR MANUFACTURING, REFORMULATION AND REPACKAGING AS A HERBICIDE ONLY.

ACTIVE INGREDIENT	
*Glyphosate, N-(phosphonomethyl) glycine in the form of its isopropylamine salt . . .	41.0%
INERT INGREDIENTS:	59.0%
	100.0%

*Contains 480 grams per litre or 4 pounds per U.S. gallon of the active ingredient, glyphosate, in the form of its isopropylamine salt. Equivalent to 356 grams per litre or 3 pounds per U.S. gallon of the acid, glyphosate.

This product is protected by U.S. Patent No. 4,405,531. Other patents pending. No license granted under any non-U.S. patent(s).

LIMIT OF WARRANTY AND LIABILITY

This Company warrants that this product conforms to the chemical description on this label. NO OTHER EXPRESS WARRANTY OR IMPLIED WARRANTY OF FITNESS FOR PARTICULAR PURPOSE OR MERCHANTABILITY IS MADE. This warranty is also subject to the conditions and limitations stated herein.

Buyer and all users shall promptly notify this Company of any claims whether based in contract, negligence, strict liability, other tort or otherwise.

Buyer and all users are responsible for all loss or damage from use or handling which results from conditions beyond the control of this Company, including, but not limited to, uses or applications in any manner not explicitly set forth in this label or application to or contact with desirable vegetation.

THE EXCLUSIVE REMEDY OF THE USER OR BUYER, AND THE LIMIT OF THE LIABILITY OF THIS COMPANY OR ANY OTHER SELLER FOR ANY AND ALL LOSSES, INJURIES OR DAMAGES RESULTING FROM THE USE OR HANDLING OF THIS PRODUCT (INCLUDING CLAIMS BASED IN CONTRACT, NEGLIGENCE, STRICT LIABILITY, OTHER TORT OR OTHERWISE) SHALL BE THE PURCHASE PRICE PAID BY THE USER OR BUYER FOR THE QUANTITY OF THIS PRODUCT INVOLVED, OR, AT THE ELECTION OF THIS COMPANY OR ANY OTHER SELLER, THE REPLACEMENT OF SUCH QUANTITY, OR, IF NOT ACQUIRED BY PURCHASE, REPLACEMENT OF SUCH QUANTITY. IN NO EVENT SHALL THIS COMPANY OR ANY OTHER SELLER BE LIABLE FOR ANY INCIDENTAL, CONSEQUENTIAL OR SPECIAL DAMAGES.

Buyer and all users are deemed to have accepted the terms of this LIMIT OF WARRANTY AND LIABILITY which may not be varied by any verbal or written agreement.

™Exchange is a trademark of Monsanto Company.

®Registered trademark of Monsanto Company.

EPA Reg. No. 524-339

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Monsanto®

In case of an emergency involving this product,
Call Collect, day or night, (314) 694-4000

LOT NO. PACKER NET gal

EPA Est. 524-LA-1 MONSANTO COMPANY • AGRICULTURAL PRODUCTS • ST. LOUIS, MISSOURI 63167 U.S.A. MAP-3207.01/53L

LIMIT OF WARRANTY AND LIABILITY

This Company warrants that this product conforms to the chemical description on this label. NO OTHER EXPRESS WARRANTY OR IMPLIED WARRANTY OF FITNESS FOR PARTICULAR PURPOSE OR MERCHANTABILITY IS MADE. This warranty is also subject to the conditions and limitations stated herein.

Buyer and all users shall promptly notify this Company of any claims whether based in contract, negligence, strict liability, other tort or otherwise.

Buyer and all users are responsible for all loss or damage from use or handling which results from conditions beyond the control of this Company, including, but not limited to, uses or applications in any manner not explicitly set forth in this label or application to or contact with desirable vegetation.

THE EXCLUSIVE REMEDY OF THE USER OR BUYER, AND THE LIMIT OF THE LIABILITY OF THIS COMPANY OR ANY OTHER SELLER FOR ANY AND ALL LOSSES, INJURIES OR DAMAGES RESULTING FROM THE USE OR HANDLING OF THIS PRODUCT (INCLUDING CLAIMS BASED IN CONTRACT, NEGLIGENCE, STRICT LIABILITY, OTHER TORT OR OTHERWISE) SHALL BE THE PURCHASE PRICE PAID BY THE USER OR BUYER FOR THE QUANTITY OF THIS PRODUCT INVOLVED, OR, AT THE ELECTION OF THIS COMPANY OR ANY OTHER SELLER, THE REPLACEMENT OF SUCH QUANTITY, OR, IF NOT ACQUIRED BY PURCHASE, REPLACEMENT OF SUCH QUANTITY. IN NO EVENT SHALL THIS COMPANY OR ANY OTHER SELLER BE LIABLE FOR ANY INCIDENTAL, CONSEQUENTIAL OR SPECIAL DAMAGES.

Buyer and all users are deemed to have accepted the terms of this LIMIT OF WARRANTY AND LIABILITY which may not be varied by any verbal or written agreement.

*Shackle is a registered trademark of Monsanto Company

MONSANTO COMPANY
AGRICULTURAL PRODUCTS
ST. LOUIS, MISSOURI 63167 U.S.A.

MAP-2233.12/53L

PRECAUTIONARY STATEMENTS

Hazards to Humans and Domestic Animals

Keep out of reach of children.

DANGER!

CAUSES IRREVERSIBLE EYE DAMAGE.
HARMFUL IF SWALLOWED OR INHALED.
MAY CAUSE SKIN IRRITATION.
Do not get in eyes, on skin or on clothing.
Wear goggles or face shield.
Avoid breathing vapor or spray mist.
Wash thoroughly with soap and water after handling.
Remove contaminated clothing and wash before reuse.
FIRST AID: IF IN EYES, immediately flush with plenty of water for at least 15 minutes. Get medical attention.
IF ON SKIN, immediately flush with plenty of water. Remove contaminated clothing before reuse.
IF SWALLOWED, this product will cause gastrointestinal tract irritation. Immediately dilute by swallowing water or milk. Get medical attention.
NOTE TO PHYSICIAN: Probable mucosal damage may contraindicate the use of gastric lavage.
IF INHALED, remove individual to fresh air. Get medical attention if breathing difficulty develops.

In case of an emergency involving this product,
Call Collect, day or night (314) 694-4000.

Environmental Hazards

Do not apply directly to water, to areas where surface water is present or to intertidal areas below the mean high water mark. Do not contaminate water when disposing of equipment washwaters.

Physical or Chemical Hazards

Solutions of this product should be mixed and stored using only stainless steel, aluminum, fiberglass, plastic or plastic-lined steel containers.

DO NOT MIX OR STORE THIS PRODUCT OR SOLUTIONS OF THIS PRODUCT IN GALVANIZED STEEL OR UNLINED STEEL (EXCEPT STAINLESS STEEL) CONTAINERS OR SPRAY TANKS.

This product or solutions of this product react with such containers and tanks to produce hydrogen gas which may form a highly combustible gas mixture. This gas mixture could flash or explode, causing serious personal injury, if ignited by open flame, spark, welder's torch, lighted cigarette or other ignition source.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in any manner inconsistent with its labeling.

Storage and Disposal

Do not contaminate water, foodstuffs, feed or seed by storage or disposal.

DISPOSAL:

Wastes resulting from the use of this product that cannot be used or chemically reprocessed should be disposed of in a landfill approved for pesticide disposal or in accordance with applicable Federal, state or local procedures.

Emptied container retains vapor and product residue. Observe all labeled safeguards until container is cleaned, reconditioned or destroyed. DO NOT CUT OR WELD ON OR NEAR THIS CONTAINER.

Do not reuse container. Triple rinse container. Then puncture and dispose of in a sanitary landfill, or by incineration, or, if allowed by state and local authorities, by burning. If burned, stay out of smoke.

FOR REFORMULATION AS A HERBICIDE ONLY.

CONCENTRATE

SHACKLE® C

135

HERBICIDE BY **Monsanto**

For formulation of products (not to exceed 10% active ingredient) for weed and grass control in industrial, residential and ornamental areas.

Read the entire label before using this product.

Read "LIMIT OF WARRANTY AND LIABILITY" before buying or using. If terms are not acceptable, return at once unopened.

Keep out of reach of children.

DANGER! Read precautions on side panel.

In case of an emergency involving this product,
Call Collect, day or night, (314) 694-4000.

ACTIVE INGREDIENT:	
*Glyphosate, N-(phosphonomethyl) glycine, in the form of its isopropylamine salt	41.0%
INERT INGREDIENTS:	59.0%
	100.0%

*Contains 480 grams per litre or 4 pounds per U.S. gallon of the active ingredient glyphosate, in the form of its isopropylamine salt. Equivalent to 356 grams per litre or 3 pounds per U.S. gallon of the acid, glyphosate.

EPA Reg. No. 524-339

EPA Est. No. 524-LA-1

NET 54 U.S. GAL.

10.13.84

BAB

PRECAUTIONARY STATEMENTS

Hazards to Humans and Domestic Animals

Keep out of reach of children.

DANGER!

CAUSES IRREVERSIBLE EYE DAMAGE.
HARMFUL IF SWALLOWED OR INHALED.
MAY CAUSE SKIN IRRITATION.
Do not get in eyes, on skin or on clothing.
Wear goggles or face shield.
Avoid breathing vapor or spray mist.
Wash thoroughly with soap and water after handling.
Remove contaminated clothing and wash before reuse.

FIRST AID: IF IN EYES, immediately flush with plenty of water for at least 15 minutes. Get medical attention.

IF ON SKIN, immediately flush with plenty of water. Remove contaminated clothing. Wash clothing before reuse.

IF SWALLOWED, this product will cause gastrointestinal tract irritation. Immediately dilute by swallowing water or milk. Get medical attention.

NOTE TO PHYSICIAN: Probable mucosal damage may contraindicate the use of gastric lavage.

IF INHALED, remove individual to fresh air. Get medical attention if breathing difficulty develops.

In case of an emergency involving this product, Call Collect, day or night (314) 694-4000.

Environmental Hazards

Do not apply directly to water, to areas where surface water is present or to intertidal areas below the mean high water mark. Do not contaminate water when disposing of equipment washwaters.

Physical or Chemical Hazards

Solutions of this product should be mixed and stored using only stainless steel, aluminum, fiberglass, plastic and plastic-lined steel containers.

DO NOT MIX OR STORE THIS PRODUCT OR SOLUTIONS OF THIS PRODUCT IN GALVANIZED STEEL OR UNLINED STEEL (EXCEPT STAINLESS STEEL) CONTAINERS OR SPRAY TANKS.

This product or solutions of this product react with such containers and tanks to produce hydrogen gas which may form a highly combustible gas mixture. This gas mixture could flash or explode, causing serious personal injury, if ignited by open flame, spark, welder's torch, lighted cigarette or other ignition source.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in any manner inconsistent with its labeling.

Storage and Disposal

Do not contaminate water, foodstuffs, feed or seed by storage or disposal.

DISPOSAL:
Wastes resulting from the use of this product that cannot be used or chemically reprocessed should be disposed of in a landfill approved for pesticide disposal or in accordance with applicable Federal, state or local procedures.

Emptied container retains vapor and product residue. Observe all labeled safeguards until container is cleaned, reconditioned or destroyed. DO NOT CUT OR WELD ON OR NEAR THIS CONTAINER.

Do not reuse container. Triple rinse container. Then puncture and dispose of in a sanitary landfill, or by incineration, or, if allowed by state and local authorities, by burning. If burned, stay out of smoke.

FOR MANUFACTURING, REFORMULATION AND REPACKAGING AS A HERBICIDE ONLY.

LIMIT OF WARRANTY AND LIABILITY

This Company warrants that this product conforms to the chemical description on this label. NO OTHER EXPRESS WARRANTY OR IMPLIED WARRANTY OF FITNESS FOR PARTICULAR PURPOSE OR MERCHANTABILITY IS MADE. This warranty is also subject to the conditions and limitations stated herein.

Buyer and all users shall promptly notify this Company of any claims whether based in contract, negligence, strict liability, other tort or otherwise.

Buyer and all users are responsible for all loss or damage from use or handlnig which results from conditions beyond the control of this Company, including, but not limited to, uses or applications in any manner not explicitly set forth in this label or application to or contact with desirable vegetation.

THE EXCLUSIVE REMEDY OF THE USER OR BUYER, AND THE LIMIT OF THE LIABILITY OF THIS COMPANY OR ANY OTHER SELLER FOR ANY AND ALL LOSSES, INJURIES OR DAMAGES RESULTING FROM THE USE OR HANDLING OF THIS PRODUCT (INCLUDING CLAIMS BASED IN CONTRACT, NEGLIGENCE, STRICT LIABILITY, OTHER TORT OR OTHERWISE) SHALL BE THE PURCHASE PRICE PAID BY THE USER OR BUYER FOR THE QUANTITY OF THIS PRODUCT INVOLVED, OR, AT THE ELECTION OF THIS COMPANY OR ANY OTHER SELLER, THE REPLACEMENT OF SUCH QUANTITY, OR, IF NOT ACQUIRED BY PURCHASE, REPLACEMENT OF SUCH QUANTITY. IN NO EVENT SHALL THIS COMPANY OR ANY OTHER SELLER BE LIABLE FOR ANY INCIDENTAL, CONSEQUENTIAL OR SPECIAL DAMAGES.

Buyer and all users are deemed to have accepted the terms of this LIMIT OF WARRANTY AND LIABILITY which may not be varied by any verbal or written agreement.

In case of an emergency involving this product, Call Collect, day or night (314) 694-4000.

MONSANTO COMPANY
AGRICULTURAL PRODUCTS
ST. LOUIS, MISSOURI 63167 U.S.A.

EXCHANGE™

HERBICIDE BY Monsanto

137

NOT REVIEWED
In Accordance with PR Notice 82-2.
Based on Draft Labeling Dated

Read the entire label before using this product.

Read "LIMIT OF WARRANTY AND LIABILITY" before buying or using. If terms are not acceptable, return at once unopened.

Keep out of reach of children.

DANGER! Read precautions on side panel.

NET 54 U.S. GAL.

ACTIVE INGREDIENT:	
*Isopropylamine salt of glyphosate	41.0%
INERT INGREDIENTS:	59.0%
	100.0%

*Contains 480 grams per litre or 4 pounds per U.S. gallon of the active ingredient isopropylamine salt of N-(phosphonomethl)glycine. Equivalent to 356 grams per litre or 3 pounds per U.S. gallon of the acid, glyphosate.

Product protected by U.S. Patent No. 4,405,531. Other patents are pending. No license granted under any non-U.S. patent(s).

EPA Reg. No. 524-339
EPA Est. No. 524-LA-1

MAP-2975.01/53L

NOT REVIEWED
In Accordance with PR Notice 82-2.
Based on Draft Labeling Dated

Monsanto

Monsanto Company
Suite 1100
700 14th Street, N.W.
Washington, D.C. 20005

May 18, 1994

Office of Pesticide Programs - H7504C
Document Processing Desk
U.S. Environmental Protection Agency
Room 226A, Crystal Mall #2
1921 Jefferson Davis Highway
Arlington, Virginia 22202

Attention: Mr. Robert J. Taylor
Product Manager (25)

Subject: **Exchange™ Herbicide (EPA Reg. No. 524-339)**
Submit Final Printed Container Label

Dear Sir:

Attached are five (5) copies of the final printed label of Exchange Herbicide for your file. This product is for manufacturing use only and does not require a Worker Protection Standard language.

If you have any questions regarding this submission, please contact Dr. Russell Schneider at our Washington office or me at 314-694-2124.

Sincerely,

Lydia A. Suba
Registration Manager

cc: R.P. Schneider
D.M. Fee-White

TELEPHONE: (202) 783-2460 FACSIMILE: (202) 783-2468

Please read Instructions on reverse before completing form.

Form Approved. OMB No. 2070-0060. Approval expires 11-30-93

(A) EPA

United States Environmental Protection Agency
Office of Pesticide Programs (H7505C)
Washington, DC 20460

Application for Pesticide:

[ ] Registration
[ ] Amendment
[X] Other

OPP Identifier Number: 207660

Section I

1. Company/Product Number: 524-339

2. EPA Product Manager: Robert J. Taylor
PM#: 25

3. Proposed Classification: [X] None [ ] Restricted

4. Company/Product (Name): Exchange™ Herbicide

5. Name and Address of Applicant *(Include ZIP Code)*:
Monsanto Company
700 14th Street, N.W., Suite 1100
Washington, DC 20005
[ ] *Check if this is a new address*

6. **Expedited Review.** In accordance with FIFRA Section 3(c)(3)(b)(i), my product is similar or identical in composition and labeling to:
EPA Reg. No. _____
Product Name _____

Section II

[ ] Amendment - Explain below
[ ] Resubmission in response to Agency letter dated _____.
[ ] Notification - Explain below.

[X] Final printed labels in response to Agency letter dated _____
[ ] "Me Too" Application.
[ ] Other - explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

Submit final printed label

Section III

1. **Material This Product Will Be Packaged In:**

Child-Resistant Packaging	Unit Packaging	Water Soluble Packaging	2. Type of Container
[ ] Yes* [X] No	[ ] Yes [X] No	[ ] Yes [X] No	[ ] Metal [ ] Plastic [ ] Glass [ ] Paper [ ] Other (Specify) _____
	If "Yes," Unit Package wgt. / No. per container	If "Yes," Package wgt. / No. per container	

* ***Certification must be submitted.***

3. Location of Net Contents Information: [ ] Label [X] Container

4. Size(s) of Retail Container: 54 gal

5. Location of Label Directions: [ ] On Label [ ] On Labeling accompanying product

6. Manner In Which Label Is Affixed To Product: [ ] Lithograph [ ] Paper glued [ ] Stenciled [ ] Other (_____)

Section IV

1. Contact Point *(Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)*

Name	Title	Telephone No. (Include Area Code)
Dr. Russell P. Schneider	Agricultural Regulation Director	(202) 783-2460

Certification

I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

6. Date Application Received (Stamped)

2. Signature: Lydia A. Suba

3. Title: Registration Manager

4. Typed Name: Lydia A. Suba

5. Date: 5/18/94

EPA Form 8570-1 (Rev. 12-90) **Previous editions are obsolete.** White - EPA File Copy (original) Yellow - Applicant copy

PAPERWORK REDUCTION ACT NOTICE and INSTRUCTIONS

PAPERWORK REDUCTION ACT NOTICE: Public reporting burden for this collection of information is estimated to average 0.85 hour per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to Chief, Information Policy Branch, PM-223, U.S. Environmental Protection Agency, 401 M Street, SW, Washington, DC 20460; and to the Office of Information and Regulatory Affairs, Office of Management and Budget, Washington, DC 20503.

INSTRUCTIONS: This form is to be used for all applications for new registration, end use reregistration, amendment, resubmission, to applications for notifications, final printed labeling, reregistration, etc. In order to process an application for a new registration submitted on this form, the following material must accompany the application:

1. Certification with Respect to Citation of Data (EPA Form 8570-29). [If not exempted by 40 CFR 152.81 (b) (4)];
2. Confidential Statement of Formula (EPA Form 8570-4);
3. Formulator's Exemption Statement (EPA Form 8570-27);
4. Five copies of draft labeling;
5. Three copies of any data submitted;
6. Authorization letter where applicable;
7. Matrices where applicable.

Submission of Labeling - Labeling should first be submitted in the form of draft labels with all applications for new registration. Such draft labels may be in the form of typed label text on 8.5 x 11 inch paper or a mockup of the proposed label. If prepared as a mockup, it should be constructed in such a way as to facilitate storage in an 8.5 x 11 inch file. Mockup labels significantly smaller than 8.5 x 11 inches should be mounted on 8.5 x 11 inch paper for submission.
Submission of Data - Data submitted in support of this application must be submitted in accordance with PR Notice 86-5.

SPECIFIC INSTRUCTIONS: Please read the instructions listed below before completing this application. First determine the type of registration action, listed in Block A, for which you are submitting this application. For applications submitted in connection with New Registration actions, Sections I, III, and IV must be completed by the applicant. For applications submitted in connection with amended registration actions, resubmissions, notifications, reregistrations, etc., Sections I, II, and IV must be completed by the applicant.
Block A - Check the appropriate action for which you are submitting this form.

SECTION I - This section must be completed, as applicable, for all registration actions.

1. **Company/Product Number** - Insert your **Company Number**, if one has been assigned by EPA. This number may have been assigned to you as a basic registrant, a distributor, or as an establishment. If your product is registered, insert the **Product Number.**
2. **EPA Product Manager** - If known, fill in the name and PM number of the EPA Product Manager.
3. **Proposed Classification** - Specify the proposed classification of this product.
4. **Product Name** - Enter the complete product name of this pesticide as it will appear on the label. The name must be specific to this product only. Duplication of names is not permitted among products of the same company. Do not include any brand name or company line designations.
5. **Name and Address of Applicant** - The name of the firm or person and address shown in your application is the person or firm to whom the registration will be issued. If you are acting in behalf of another party, you must submit authorization from that party to act for them in registration matters. An applicant not residing in the United States must have an authorized agent residing in the United States to act for them in all registration matters. The name and complete mailing address of such an agent must accompany this application.
6. **Expedited Review** - FIFRA section 3 (c) 3 (B) provides for expedited review of applications for registration, or amendments to existing registrations, that are similar or identical to other pesticide products that are currently registered with the EPA. In order for your application to be eligible for expedited review, you must provide us with the EPA Registration Number and product name of the product you believe is similar to or identical to your product. The product must be similar or identical in both formulation and labeled uses.

SECTION II - This section must be completed for all applications submitted to amend the registration only of a currently registered product (Amendment), for a resubmission in response to an Agency letter, for notifications to the Agency, for the submission of final printed labeling, for reregistration and for any other action that pertains to a specific EPA-registered product. This section is not to be used for a new application for registration.

1. **Subject of submission** - Check the applicable block and provide the Agency letter date if appropriate. Provide a brief explanation of the purpose(s) for the submission, such as "the addition of a site, pest or crop (specify)"; "amend the Confidential Statement of Formula by..."; "reregistration submission"; general label revision of use directions." Attach a separate page if additional space is needed.

SECTION III (Packaging and Container Information) - This Section must be completed for all applications submitted in connection with new registration or applicable amendments.

1. **Type of Packaging** - Check the appropriate block if your product will be packaged in the indicated packaging types. Indicate the size of the individual packets and number per retail container.
2. **Type of Retail Container** - Indicate type of container in which product will be marketed.
3. **Location of Net Contents** - Specify the net contents of all retail containers for your product.
4. **Size(s) of Retail Container** - Specify the net contents of all retail containers for your product.
5. **Location of Use Directions** - Indicate the location of the use directions for your product.
6. **Manner in which label is affixed to product** - Indicate the method product label is attached to retail container.

SECTION IV (Contact Point) - This Section must be completed for all applications for Registration actions, i.e., new products registration, resubmission, "me-too," reregistration, etc.

1-5. Self-explanatory.
6. EPA Use Only.

EXCHANGE™

HERBICIDE BY Monsanto

Read the entire label before using this product.

Read "LIMIT OF WARRANTY AND LIABILITY" before buying or using. If terms are not acceptable, return at once unopened.

PRECAUTIONARY STATEMENTS

Hazards to Humans and Domestic Animals

Keep out of reach of children.

DANGER!

CAUSES IRREVERSIBLE EYE DAMAGE.
HARMFUL IF SWALLOWED OR INHALED.
MAY CAUSE SKIN IRRITATION.
Do not get in eyes, on skin or on clothing.
Wear goggles or face shield.
Avoid breathing vapor or spray mist.
Wash thoroughly with soap and water after handling.
Remove contaminated clothing and wash before reuse.

FIRST AID: IF IN EYES, immediately flush with plenty of water for at least 15 minutes. Get medical attention.

IF ON SKIN, immediately flush with plenty of water. Remove contaminated clothing. Wash clothing before reuse.

IF SWALLOWED, this product will cause gastrointestinal tract irritation. Immediately dilute by swallowing water or milk. Get medical attention.

NOTE TO PHYSICIAN: Probable mucosal damage may contraindicate the use of gastric lavage.

IF INHALED, remove individual to fresh air. Get medical attention if breathing difficulty develops.

In case of an emergency involving this product, Call Collect, day or night, (314) 694-4000.

Environmental Hazards

Do not apply directly to water, to areas where surface water is present or to intertidal areas below the mean high water mark. Do not contaminate water when disposing of equipment washwaters.

Physical or Chemical Hazards

Solutions of this product should be mixed and stored using only stainless steel, aluminum, fiberglass, plastic or plastic-lined steel containers.

DO NOT MIX OR STORE THIS PRODUCT OR SOLUTIONS OF THIS PRODUCT IN GALVANIZED STEEL OR UNLINED STEEL (EXCEPT STAINLESS STEEL) CONTAINERS OR SPRAY TANKS.

This product or solutions of this product react with such containers and tanks to produce hydrogen gas which may form a highly combustible gas mixture. This gas mixture could flash or explode, causing serious personal injury, if ignited by open flame, spark, welder's torch, lighted cigarette or other ignition source.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in any manner inconsistent with its labeling.

Storage and Disposal

Do not contaminate water, foodstuffs, feed or seed by storage of disposal.

DISPOSAL:
Wastes resulting from the use of this product that cannot be used or chemically reprocessed should be disposed of in a landfill approved for pesticide disposal or in accordance with applicable Federal, state or local procedures.

Emptied container retains vapor and product residue. Observe all labeled safeguards until container is cleaned, reconditioned or destroyed. DO NOT CUT OR WELD ON OR NEAR THIS CONTAINER.

Triple rinse emptied bulk containers. Then offer for recycling or reconditioning, or dispose of in a manner approved by state and local authorities.

FOR MANUFACTURING, REFORMULATION AND REPACKAGING AS A HERBICIDE ONLY.

ACTIVE INGREDIENT	
*Glyphosate, N-(phosphonomethyl) glycine in the form of its isopropylamine salt . . .	41.0%
INERT INGREDIENTS:	59.0%
	100.0%

*Contains 480 grams per litre or 4 pounds per U.S. gallon of the active ingredient, glyphosate, in the form of its isopropylamine salt. Equivalent to 356 grams per litre or 3 pounds per U.S. gallon of the acid, glyphosate.

This product is protected by U.S. Patent No. 4,405,531. Other patents pending. No license granted under any non-U.S. patent(s).

LIMIT OF WARRANTY AND LIABILITY

This Company warrants that this product conforms to the chemical description on this label. NO OTHER EXPRESS WARRANTY OR IMPLIED WARRANTY OF FITNESS FOR PARTICULAR PURPOSE OR MERCHANTABILITY IS MADE. This warranty is also subject to the conditions and limitations stated herein.

Buyer and all users shall promptly notify this Company of any claims whether based in contract, negligence, strict liability, other tort or otherwise.

Buyer and all users are responsible for all loss or damage from use or handling which results from conditions beyond the control of this Company, including, but not limited to, uses or applications in any manner not explicitly set forth in this label or application to or contact with desirable vegetation.

THE EXCLUSIVE REMEDY OF THE USER OR BUYER, AND THE LIMIT OF THE LIABILITY OF THIS COMPANY OR ANY OTHER SELLER FOR ANY AND ALL LOSSES, INJURIES OR DAMAGES RESULTING FROM THE USE OR HANDLING OF THIS PRODUCT (INCLUDING CLAIMS BASED IN CONTRACT, NEGLIGENCE, STRICT LIABILITY, OTHER TORT OR OTHERWISE) SHALL BE THE PURCHASE PRICE PAID BY THE USER OR BUYER FOR THE QUANTITY OF THIS PRODUCT INVOLVED, OR, AT THE ELECTION OF THIS COMPANY OR ANY OTHER SELLER, THE REPLACEMENT OF SUCH QUANTITY, OR, IF NOT ACQUIRED BY PURCHASE, REPLACEMENT OF SUCH QUANTITY. IN NO EVENT SHALL THIS COMPANY OR ANY OTHER SELLER BE LIABLE FOR ANY INCIDENTAL, CONSEQUENTIAL OR SPECIAL DAMAGES.

Buyer and all users are deemed to have accepted the terms of this LIMIT OF WARRANTY AND LIABILITY which may not be varied by any verbal or written agreement.

™Exchange is a trademark of Monsanto Company.

® Registered trademark of Monsanto Company.

EPA Reg. No. 524-339

Monsanto®

In case of an emergency involving this product,
Call Collect, day or night, (314) 694-4000

NOT REVIEWED
In Accordance with PR Notice 82-2,
Based on Draft Labeling Dated 4/2/92

LOT NO. PACKER NET gal

EPA Est. 524-LA-1 MONSANTO COMPANY • AGRICULTURAL PRODUCTS • ST. LOUIS, MISSOURI 63167 U.S.A. MAP-3207.01/53L

Please read Instructions on reverse before completing form.

Form Approved. OMB No. 2070-0060. Approval expires 11-30-93

(A) EPA

United States Environmental Protection Agency
Office of Pesticide Programs (H7505C)
Washington, DC 20460

Application for Pesticide:

[ ] Registration
[ ] Amendment
[X] Other

OPP Identifier Number: 156966

Section I

1. Company/Product Number: Monsanto/524-339
2. EPA Product Manager: Robert J. Taylor
   PM#: 25
3. Proposed Classification: [X] None [ ] Restricted
4. Company/Product (Name): Exchange™ Herbicide
5. Name and Address of Applicant *(Include ZIP Code)*:
   Monsanto Company
   700 14th Street, N.W., Suite 1100
   Washington, D.C. 20005
   [ ] *Check if this is a new address*
6. **Expedited Review.** In accordance with FIFRA Section 3(c)(3)(b)(i), my product is similar or identical in composition and labeling to:
   EPA Reg. No. _____
   Product Name _____

Section II

[ ] Amendment - Explain below
[ ] Resubmission in response to Agency letter dated _____
[ ] Notification - Explain below.
[X] Final printed labels in response to Agency letter dated 4/2/92
[ ] "Me Too" Application.
[ ] Other - explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

Section III

1. **Material This Product Will Be Packaged In:**

Child-Resistant Packaging	Unit Packaging	Water Soluble Packaging	2. Type of Container
[ ] Yes* [ ] No	[ ] Yes [ ] No	[ ] Yes [ ] No	[ ] Metal [ ] Plastic [ ] Glass [ ] Paper [ ] Other (Specify) _____
* *Certification must be submitted.*	If "Yes," Unit Package wgt. / No. per container	If "Yes," Package wgt. / No. per container	

3. Location of Net Contents Information: [ ] Label [ ] Container
4. Size(s) of Retail Container
5. Location of Label Directions: [ ] On Label [ ] On Labeling accompanying product
6. Manner In Which Label Is Affixed To Product: [ ] Lithograph [ ] Paper glued [ ] Stenciled [ ] Other (_____)

Section IV

1. Contact Point *(Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)*

Name	Title	Telephone No. (Include Area Code)
Russell P. Schneider, Ph.D.	Agricultural Regulation Director	(202) 783-2460

Certification

I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

6. Date Application Received (Stamped)

2. Signature	3. Title	4. Typed Name	5. Date
Lydia A. Suba	Registration Manager	Lydia A. Suba	8/25/92

EPA Form 8570-1 (Rev. 12-90) **Previous editions are obsolete.** White - EPA File Copy (original) Yellow - Applicant copy

PAPERWORK REDUCTION ACT NOTICE and INSTRUCTIONS

PAPERWORK REDUCTION ACT NOTICE: Public reporting burden for this collection of information is estimated to average 0.85 hour per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to Chief, Information Policy Branch, PM-223, U.S. Environmental Protection Agency, 401 M Street, SW, Washington, DC 20460; and to the Office of Information and Regulatory Affairs, Office of Management and Budget, Washington, DC 20503.

INSTRUCTIONS: This form is to be used for all applications for new registration, end use reregistration, amendment, resubmission, to applications for notifications, final printed labeling, reregistration, etc. In order to process an application for a new registration submitted on this form, the following material must accompany the application:

1. Certification with Respect to Citation of Data (EPA Form 8570-29). [If not exempted by 40 CFR 152.81 (b) (4)];
2. Confidential Statement of Formula (EPA Form 8570-4);
3. Formulator's Exemption Statement (EPA Form 8570-27);
4. Five copies of draft labeling;
5. Three copies of any data submitted;
6. Authorization letter where applicable;
7. Matrices where applicable.

Submission of Labeling - Labeling should first be submitted in the form of draft labels with all applications for new registration. Such draft labels may be in the form of typed label text on 8.5 x 11 inch paper or a mockup of the proposed label. If prepared as a mockup, it should be constructed in such a way as to facilitate storage in an 8.5 x 11 inch file. Mockup labels significantly smaller than 8.5 x 11 inches should be mounted on 8.5 x 11 inch paper for submission.
Submission of Data - Data submitted in support of this application must be submitted in accordance with PR Notice 86-5.

SPECIFIC INSTRUCTIONS: Please read the instructions listed below before completing this application. First determine the type of registration action, listed in Block A, for which you are submitting this application. For applications submitted in connection with New Registration actions, Sections I, III, and IV must be completed by the applicant. For applications submitted in connection with amended registration actions, resubmissions, notifications, reregistrations, etc., Sections I, II, and IV must be completed by the applicant.
Block A - Check the appropriate action for which you are submitting this form.

SECTION I - This section must be completed, as applicable, for all registration actions.

1. **Company/Product Number** - Insert your **Company Number**, if one has been assigned by EPA. This number may have been assigned to you as a basic registrant, a distributor, or as an establishment. If your product is registered, insert the **Product Number**.
2. **EPA Product Manager** - If known, fill in the name and PM number of the EPA Product Manager.
3. **Proposed Classification** - Specify the proposed classification of this product.
4. **Product Name** - Enter the complete product name of this pesticide as it will appear on the label. The name must be specific to this product only. Duplication of names is not permitted among products of the same company. Do not include any brand name or company line designations.
5. **Name and Address of Applicant** - The name of the firm or person and address shown in your application is the person or firm to whom the registration will be issued. If you are acting in behalf of another party, you must submit authorization from that party to act for them in registration matters. An applicant not residing in the United States must have an authorized agent residing in the United States to act for them in all registration matters. The name and complete mailing address of such an agent must accompany this application.
6. **Expedited Review** - FIFRA section 3 (c) 3 (B) provides for expedited review of applications for registration, or amendment to existing registrations, that are similar or identical to other pesticide products that are currently registered with the EPA. In order for your application to be eligible for expedited review, you must provide us with the EPA Registration Number and product name of the product you believe is similar to or identical to your product. The product must be similar or identical in both formulation and labeled uses.

SECTION II - This section must be completed for all applications submitted to amend the registration only of a currently registered product (Amendment), for a resubmission in response to an Agency letter, for notifications to the Agency, for the submission of final printed labeling, for reregistration and for any other action that pertains to a specific EPA-registered product. This section is not to be used for a new application for registration.

1. **Subject of submission** - Check the applicable block and provide the Agency letter date if appropriate. Provide a brief explanation of the purpose(s) for the submission, such as "the addition of a site, pest or crop (specify)"; "amend the Confidential Statement of Formula by..."; "reregistration submission"; general label revision of use directions." Attach a separate page if additional space is needed.

SECTION III (Packaging and Container Information) - This Section must be completed for all applications submitted in connection with new registration or applicable amendments.

1. **Type of Packaging** - Check the appropriate block if your product will be packaged in the indicated packaging types. Indicate the size of the individual packets and number per retail container.
2. **Type of Retail Container** - Indicate type of container in which product will be marketed.
3. **Location of Net Contents** - Specify the net contents of all retail containers for your product.
4. **Size(s) of Retail Container** - Specify the net contents of all retail containers for your product.
5. **Location of Use Directions** - Indicate the location of the use directions for your product.
6. **Manner in which label is affixed to product** - Indicate the method product label is attached to retail container.

SECTION IV (Contact Point) - This Section must be completed for all applications for Registration actions, i.e., new products registration, resubmission, "me-too," reregistration, etc.

1-5. Self-explanatory.
6. EPA Use Only.

★U.S.GPO:1992-0-[illegible]/41065

Monsanto

Monsanto Company
Suite 1100
700 14th Street, N.W.
Washington, D.C. 20005

August 25, 1992

Office of Pesticide Programs
Document Processing Desk (AMEND)
U.S. Environmental Protection Agency
1921 Jefferson Davis Highway
Crystal Mall #2, Room 266A
Arlington, Virginia 22202

Attention: Mr. Robert J. Taylor
Product Manager (25)

Subject: EXCHANGE™ Herbicide (EPA Reg. No. 524-339)
Submission of Final Printed Label

Dear Sir:

EXCHANGE Herbicide is a brandname which was approved by the Agency on October 31, 1988 for Shackle® C Herbicide. On January 30, 1992, the Agency informed Monsanto that Shackle C Herbicide requires a "Danger" signal word. Amendment to change the signal word of Shackle C was submitted on March 10, 1992 for review. The label was approved and stamped on April 2, 1992.

Since Shackle C Herbicide is the base formulation for Exchange, the signal word for Exchange was correspondingly changed. Enclosed are five (5) copies of the Exchange Herbicide label with the required "Danger" signal word and the appropriate precautionary language. In addition, the new wetlands statement has also been incorporated into the Environmental Hazards section of the label and two (2) patent numbers which are no longer in effect were deleted.

If you have any questions regarding this submission, please contact Dr. Russell Schneider at our Washington office or me at 314-694-2124.

Sincerely,

Lydia A. Suba
Registration Manager

TELEPHONE: (202) 783-2460 FACSIMILE: (202) 783-2468

APR - 2 1992

Dr. Sheila A. Schuette
Monsanto Company
700 14th Street, NW., Suite 1100
Washington, DC 20005

Dear Dr. Schuette:

Subject: Shackle C Herbicide (Change Signal Word to "Danger")
EPA Registration No. 524-339
Your Letter Dated March 10, 1992

The amended labeling submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, is acceptable. Please submit five (5) copies of your final printed labeling before you release the product for shipment. A stamped copy of the labeling is enclosed for your records.

Sincerely yours,

Robert J. Taylor
Product Manager (25)
Fungicide-Herbicide Branch
Registration Division (H7505C)

Enclosure

56075:I:Taylor:WP25-4:KEVRIC:03/30/92:04/30/92:rj:dd:rj

CONCURRENCES								
SYMBOL	H7505C							
SURNAME	VKWalker							
DATE	4/1/92							

EPA Form 1320-1 (12-70) OFFICIAL FILE COPY

Monsanto

Monsanto Company
Suite 1100
700 14th Street, N.W.
Washington, D.C. 20005

March 10, 1992

Office of Pesticide Programs - H7504C
Document Processing Desk
U.S. Environmental Protection Agency
Room 226A, Crystal Mall #2
1921 Jefferson Davis Highway
Arlington, Virginia 22202

Attention: Mr. Robert J. Taylor
Product Manager (25)

Subject: **Shackle® C Herbicide (EPA Reg. No. 524-339)**
Submission of Amended Labels

Dear Sir:

Monsanto is submitting amended container labels for Shackle C herbicide for Agency review and approval. Shackle C herbicide is a manufacturing use product that contains 41% of the isopropylamine salt of glyphosate and [redacted] of MON-0818 ethoxylated tallowamine surfactant. On January 30, 1992, the Agency informed Monsanto that this formulation requires a "Danger" signal word.

Enclosed are five (5) copies each of the amended Shackle C herbicide container labels (54 gallon and no weight bulk) with the required "Danger" signal word and appropriate precautionary language. The new wetlands statement has also been incorporated into the Environmental Hazards section of the labels. Monsanto requests that these lahels be approved and stamped; the labels will be effective immediately upon receipt of Agency approval.

If you have any questions regarding this request, please contact Dr. Russ Schneider or me.

Sincerely,

Sheila A. Schuette

Sheila A. Schuette, Ph.D.
Senior Registration Specialist
(314) 694-7248

Inert ingredient information may be entitled to confidential treatment

cc: R.P. Schneider
D.P. Ward
D.E. Brock
S.D. Schuette

Please read Instructions on reverse before completing form.

Form Approved. OMB No. 2070-0060. Approval expires 11-30-93

(A) EPA

United States Environmental Protection Agency
Office of Pesticide Programs (H7505C)
Washington, DC 20460

Application for Pesticide:

[ ] Registration
[X] Amendment
[ ] Other

OPP Identifier Number: 156757

Section I

1. Company/Product Number: Monsanto/524-339
2. EPA Product Manager: Robert J. Taylor
3. Proposed Classification: [X] None [ ] Restricted
4. Company/Product (Name): Shackle® C Herbicide
   PM#: 25
5. Name and Address of Applicant *(Include ZIP Code)*:
   Monsanto Company
   700 14th Street, N.W.
   Suite 1100
   Washington, D.C. 20005
   [ ] *Check if this is a new address*
6. **Expedited Review.** In accordance with FIFRA Section 3(c)(3)(b)(i), my product is similar or identical in composition and labeling to:
   EPA Reg. No._____
   Product Name_____

Section II

[X] Amendment - Explain below
[ ] Resubmission in response to Agency letter dated_____.
[ ] Notification - Explain below.
[ ] Final printed labels in response to Agency letter dated_____.
[ ] "Me Too" Application.
[ ] Other - explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

Submission of amended labels.

Section III

1. **Material This Product Will Be Packaged In:**

Child-Resistant Packaging	Unit Packaging	Water Soluble Packaging	2. Type of Container
[ ] Yes* [X] No	[ ] Yes [X] No	[ ] Yes [X] No	[X] Metal [ ] Plastic [ ] Glass [ ] Paper [ ] Other (Specify)_____
* *Certification must be submitted.*	If "Yes," Unit Package wgt. / No. per container	If "Yes," Package wgt. / No. per container	

3. Location of Net Contents Information: [X] Label [ ] Container
4. Size(s) of Retail Container: 54 gal, bulk
5. Location of Label Directions: [X] On Label [ ] On Labeling accompanying product
6. Manner In Which Label Is Affixed To Product: [ ] Lithograph [ ] Paper glued [ ] Stenciled [x] Other (vinyl glued)

Section IV

1. Contact Point *(Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)*

Name	Title	Telephone No. (Include Area Code)
Russell P. Schneider, Ph.D.	Agricultural Regulations Director	(202) 783-2460

Certification

I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

6. Date Application Received **(Stamped)**

2. Signature	3. Title	4. Typed Name	5. Date
Sheila A Schuette	Senior Registration Specialist	Sheila A. Schuette, Ph.D.	3/10/92

PAPERWORK REDUCTION ACT NOTICE and INSTRUCTIONS

PAPERWORK REDUCTION ACT NOTICE: Public reporting burden for this collection of information is estimated to average 0.85 hour per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to Chief, Information Policy Branch, PM-223, U.S. Environmental Protection Agency, 401 M Street, SW, Washington, DC 20460; and to the Office of Information and Regulatory Affairs, Office of Management and Budget, Washington, DC 20503.

INSTRUCTIONS: This form is to be used for all applications for new registration, end use reregistration, amendment, resubmission, to applications for notifications, final printed labeling, reregistration, etc. In order to process an application for a new registration submitted on this form, the following material must accompany the application:

1. Certification with Respect to Citation of Data (EPA Form 8570-29). [If not exempted by 40 CFR 152.81 (b) (4)];
2. Confidential Statement of Formula (EPA Form 8570-4);
3. Formulator's Exemption Statement (EPA Form 8570-27);
4. Five copies of draft labeling;
5. Three copies of any data submitted;
6. Authorization letter where applicable;
7. Matrices where applicable.

Submission of Labeling - Labeling should first be submitted in the form of draft labels with all applications for new registration. Such draft labels may be in the form of typed label text on 8.5 x 11 inch paper or a mockup of the proposed label. If prepared as a mockup, it should be constructed in such a way as to facilitate storage in an 8.5 x 11 inch file. Mockup labels significantly smaller than 8.5 x 11 inches should be mounted on 8.5 x 11 inch paper for submission.
Submission of Data - Data submitted in support of this application must be submitted in accordance with PR Notice 86-5.

SPECIFIC INSTRUCTIONS: Please read the instructions listed below before completing this application. First determine the type of registration action, listed in Block A, for which you are submitting this application. For applications submitted in connection with New Registration actions, Sections I, III, and IV must be completed by the applicant. For applications submitted in connection with amended registration actions, resubmissions, notifications, reregistrations, etc., Sections I, II, and IV must be completed by the applicant.
Block A - Check the appropriate action for which you are submitting this form.

SECTION I - This section must be completed, as applicable, for all registration actions.

1. **Company/Product Number** - Insert your **Company Number**, if one has been assigned by EPA. This number may have been assigned to you as a basic registrant, a distributor, or as an establishment. If your product is registered, insert the **Product Number**.
2. **EPA Product Manager** - If known, fill in the name and PM number of the EPA Product Manager.
3. **Proposed Classification** - Specify the proposed classification of this product.
4. **Product Name** - Enter the complete product name of this pesticide as it will appear on the label. The name must be specific to this product only. Duplication of names is not permitted among products of the same company. Do not include any brand name or company line designations.
5. **Name and Address of Applicant** - The name of the firm or person and address shown in your application is the person or firm to whom the registration will be issued. If you are acting in behalf of another party, you must submit authorization from that party to act for them in registration matters. An applicant not residing in the United States must have an authorized agent residing in the United States to act for them in all registration matters. The name and complete mailing address of such an agent must accompany this application.
6. **Expedited Review** - FIFRA section 3 (c) 3 (B) provides for expedited review of applications for registration, or amendments to existing registrations, that are similar or identical to other pesticide products that are currently registered with the EPA. In order for your application to be eligible for expedited review, you must provide us with the EPA Registration Number and product name of the product you believe is similar to or identical to your product. The product must be similar or identical in both formulation and labeled uses.

SECTION II - This section must be completed for all applications submitted to amend the registration only of a currently registered product (Amendment), for a resubmission in response to an Agency letter, for notifications to the Agency, for the submission of final printed labeling, for reregistration and for any other action that pertains to a specific EPA-registered product. This section is not to be used for a new application for registration.

1. **Subject of submission** - Check the applicable block and provide the Agency letter date if appropriate. Provide a brief explanation of the purpose(s) for the submission, such as "the addition of a site, pest or crop (specify)"; "amend the Confidential Statement of Formula by..."; "reregistration submission"; general label revision of use directions." Attach a separate page if additional space is needed.

SECTION III (Packaging and Container Information) - This Section must be completed for all applications submitted in connection with new registration or applicable amendments.

1. **Type of Packaging** - Check the appropriate block if your product will be packaged in the indicated packaging types. Indicate the size of the individual packets and number per retail container.
2. **Type of Retail Container** - Indicate type of container in which product will be marketed.
3. **Location of Net Contents** - Specify the net contents of all retail containers for your product.
4. **Size(s) of Retail Container** - Specify the net contents of all retail containers for your product.
5. **Location of Use Directions** - Indicate the location of the use directions for your product.
6. **Manner in which label is affixed to product** - Indicate the method product label is attached to retail container.

SECTION IV (Contact Point) - This Section must be completed for all applications for Registration actions, i.e., new products registration, resubmission, "me-too," reregistration, etc.

1-5. Self-explanatory.
6. EPA Use Only.

★U.S.GPO:1992-0-[illegible]7/41065

LIMIT OF WARRANTY AND LIABILITY

This Company warrants that this product conforms to the chemical description on this label. NO OTHER EXPRESS WARRANTY OR IMPLIED WARRANTY OF FITNESS FOR PARTICULAR PURPOSE OR MERCHANTABILITY IS MADE. This warranty is also subject to the conditions and limitations stated herein.

Buyer and all users shall promptly notify this Company of any claims whether based in contract, negligence, strict liability, other tort or otherwise.

Buyer and all users are responsible for all loss or damage from use or handling which results from conditions beyond the control of this Company, including, but not limited to, uses or applications in any manner not explicitly set forth in this label or application to or contact with desirable vegetation.

THE EXCLUSIVE REMEDY OF THE USER OR BUYER, AND THE LIMIT OF THE LIABILITY OF THIS COMPANY OR ANY OTHER SELLER FOR ANY AND ALL LOSSES, INJURIES OR DAMAGES RESULTING FROM THE USE OR HANDLING OF THIS PRODUCT (INCLUDING CLAIMS BASED IN CONTRACT, NEGLIGENCE, STRICT LIABILITY, OTHER TORT OR OTHERWISE) SHALL BE THE PURCHASE PRICE PAID BY THE USER OR BUYER FOR THE QUANTITY OF THIS PRODUCT INVOLVED, OR, AT THE ELECTION OF THIS COMPANY OR ANY OTHER SELLER, THE REPLACEMENT OF SUCH QUANTITY, OR, IF NOT ACQUIRED BY PURCHASE, REPLACEMENT OF SUCH QUANTITY. IN NO EVENT SHALL THIS COMPANY OR ANY OTHER SELLER BE LIABLE FOR ANY INCIDENTAL, CONSEQUENTIAL OR SPECIAL DAMAGES.

Buyer and all users are deemed to have accepted the terms of this LIMIT OF WARRANTY AND LIABILITY which may not be varied by any verbal or written agreement.

Product protected by U.S. Patent No. 4,405,531. Other patents are pending. No license granted under any non-U.S. patent.

*Shackle is a registered trademark of Monsanto Company

MONSANTO COMPANY
AGRICULTURAL PRODUCTS
ST. LOUIS, MISSOURI 63167 U.S.A.

MAP-2233.13/53L

york 2537 monsanto Shackle C 5-9-86
Disk-M-64 F-2537 P-1 Dress 68 ks

152

PRECAUTIONARY STATEMENTS

Hazards to Humans and Domestic Animals

Keep out of reach of children.

DANGER!

CAUSES IRREVERSIBLE EYE DAMAGE.
HARMFUL IF SWALLOWED OR INHALED.
MAY CAUSE SKIN IRRITATION.
Do not get in eyes, on skin or on clothing.
Wear goggles or face shield.
Avoid breathing vapor or spray mist.
Wash thoroughly with soap and water after handling.
Remove contaminated clothing and wash before reuse.
FIRST AID: IF IN EYES, immediately flush with plenty of water for at least 15 minutes. Get medical attention.
IF ON SKIN, immediately flush with plenty of water. Remove contaminated clothing. Wash clothing before reuse.
IF SWALLOWED, this product will cause gastrointestinal tract irritation. Immediately dilute by swallowing water or milk. Get medical attention.
NOTE TO PHYSICIAN: Probable mucosal damage may contraindicate the use of gastric lavage.
IF INHALED, remove individual to fresh air. Get medical attention if breathing difficulty develops.

In case of an emergency involving this product,
Call Collect, day or night (314) 694-4000.

Environmental Hazards

Do not apply directly to water, to areas where surface water is present or to intertidal areas below the mean high water mark. Do not contaminate water when disposing of equipment washwaters.

Physical or Chemical Hazards

Solutions of this product should be mixed and stored using only stainless steel, aluminum, fiberglass, plastic or plastic-lined steel containers.

DO NOT MIX OR STORE THIS PRODUCT OR SOLUTIONS OF THIS PRODUCT IN GALVANIZED STEEL OR UNLINED STEEL (EXCEPT STAINLESS STEEL) CONTAINERS OR SPRAY TANKS.

This product or solutions of this product react with such containers and tanks to produce hydrogen gas which may form a highly combustible gas mixture. This gas mixture could flash or explode, causing serious personal injury, if ignited by open flame, spark, welder's torch, lighted cigarette or other ignition source.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in any manner inconsistent with its labeling.

Storage and Disposal

Do not contaminate water, foodstuffs, feed or seed by storage or disposal.

DISPOSAL:
Wastes resulting from the use of this product that cannot be used or chemically reprocessed should be disposed of in a landfill approved for pesticide disposal or in accordance with applicable Federal, state or local procedures.

Emptied container retains vapor and product residue. Observe all labeled safeguards until container is cleaned, reconditioned or destroyed. DO NOT CUT OR WELD ON OR NEAR THIS CONTAINER.

Triple rinse emptied bulk containers. Then offer for recycling or reconditioning, or dispose of in a manner approved by state and local authorities.

FOR REFORMULATION AS A HERBICIDE ONLY

york 2537 monsanto Shackle C 5-9-86
Disk-M-64 F-2537 P-2 Dress 68 ks
Revised 5-19-86 ab
revised 2-24-92 for York 4808 on
Revised 2-26-92 ks On York 4808

CONCENTRATE

SHACKLE® C

HERBICIDE BY **Monsanto**

For formulation of products (not to exceed 10% active ingredient) for weed and grass control in industrial, residential and ornamental areas.

Read the entire label before using this product.

Read "LIMIT OF WARRANTY AND LIABILITY" before buying or using. If terms are not acceptable, return at once unopened.

Keep out of reach of children.

DANGER! Read precautions on side panel.

In case of an emergency involving this product,
Call Collect, day or night, (314) 694-4000.

ACTIVE INGREDIENT:	
*Glyphosate, N-(phosphonomethyl)glycine, in the form of its isopropylamine salt	41.0%
INERT INGREDIENTS:	59.0%
	100.0%

*Contains 480 grams per liter or 4 pounds per U.S. gallon of the active ingredient, glyphosate, in the form of its isopropylamine salt. Equivalent to 356 grams per liter or 3 pounds per U.S. gallon of the acid, glyphosate.

EPA Reg. No. 524-339

EPA Est. No. 524-LA-1

NET U.S. GAL.

FINAL PROOF

ACCEPTED
APR - 2 1992
Under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, for the pesti
registered under
EPA Reg. No. 524-339

York Typographers • FEBRUARY 25, 1992

SUBMISSION REVIEW RECORD G

1. REGISTRATION NUMBER	CYCLE	2. DATE RECEIVED (MO / DAY / YR)
524-339		03 / 11 / 92

3. 3CIO PUBLICATION NECESSARY	4. PETITION NO.	5. RECEIVED PM TEAM (MO / DAY / YR)
☐ YES ☐ NO		

6. METHOD OF SUPPORT	7. PRODUCT MANAGER	NO.	8. PROJECTED RETURN (MO / DAY / YR)
☐ 2A ☐ 2B ☐ 2C			

9. DATE PULLED	10. DATE PUBLISHED	11. ACTION TYPE	CODE	12. OUTGOING DATE (MO / DAY / YR)
3/19/92		Change Signal Word to "Danger" as req'd by TB 305		

REV SEQ.	REVIEW TYPE CODE	REVIEW TYPE	REVIEWER CODE (Initials)	SIGNATURE OF REVIEWER	COMMENT CODE	DATE REVIEW COMPLETED (MO / DAY / YR)
	A	REVIEWABILITY TEAM				
	B	PRODUCT MANAGER TEAM EFFICACY REVIEW				
	C	PRODUCT MANAGER TEAM HUMAN SAFETY REVIEW				
	D	PRODUCT MANAGER TEAM ENVIRONMENTAL SAFETY REVIEW				
	E	PRODUCT MANAGER TEAM RESUBMISSION REVIEW				
	F	PRODUCT MANAGER		UKW	NAC	03 / 19 / 92
	G	INTERAGENCY REFERRAL		Data for this already		
	H	COST-BENEFIT REVIEW		looked at by TB -		
	I	PUBLIC COMMENTS REVIEW		offer to pay does not		
	J	EEE BRANCH INSECTICIDE EFFICACY		apply when we tell		
	K	EEE BRANCH HERBICIDE EFFICACY		company to change		
	L	EEE BRANCH FUNGICIDE EFFICACY		signal Word		
	M	EEE BRANCH RODENTICIDE EFFICACY				
	N	EEE BRANCH DISINFECTANT EFFICACY				
	O	CHEMISTRY BRANCH RESIDUE CHEMISTRY				
	P	EEE BRANCH ENVIRONMENTAL CHEMISTRY				
	Q	TOXICOLOGY BRANCH HUMAN SAFETY				
	R	EEE BRANCH ENVIRONMENTAL SAFETY				
	S					
	T					

PRODUCT MANAGER SIGNATURE	TYPE OF RESPONSE	CODE

EPA Form 8570-13 (3-79)

OCT 31 1988

Mr. Roy G. Danhaus
Monsanto Company
1101 17th Street NW.
Washington, DC 20036

Dear Mr. Danhaus:

Subject: Shackle C Herbicide (Notification of Brand Name)
EPA Registration No. 524-339
Your Letter Dated June 29, 1988

Your notification of the additional brand name "Exchange" for the subject product has been received and is acceptable. A stamped copy of the labeling bearing this name is enclosed for your records.

Sincerely yours,

Robert J. Taylor
Product Manager (25)
Fungicide-Herbicide Branch
Registration Division (TS-767C)

Enclosure

52716:I:Taylor:T-8:KENCO:10/20/88:11/01/88:de:EK:VO:CT

CONCURRENCES								
SYMBOL	TS-767C							
SURNAME	WKWalker							
DATE	10/28/88							

EPA Form 1320-1 (12-70) OFFICIAL FILE COPY

Monsanto

Monsanto Company
1101 17th Street, N.W.
Washington, D.C. 20036
Phone: (202) 452-8880

June 29, 1988

Director
Registration Division (TS767C)
Office of Pesticide Programs
U.S. Environmental Protection Agency
1921 Jefferson Davis Highway
Crystal Mall #2, Room 726
Arlington, Virginia 22202

Attention: Mr. Robert J. Taylor
Product Manager (25)

Subject: Notification of New
Product Name
EXCHANGE™ Herbicide
EPA Reg. No. 524-339

Dear Sir:

On September 24, 1980, the Agency approved SHACKLE® C Herbicide and assigned it the registration number 524-339. SHACKLE® C is identical to ROUNDUP Herbicide (EPA Reg. No. 524-308), both products containing 41% isopropylamine salt of glyphosate active ingredient.

The SHACKLE® C label contains the statement "For formulation of products (not to exceed 10% active ingredient) for weed and grass control in industrial, residential and ornamental areas." The EXCHANGE™ Herbicide label will not restrict reformulation to products containing up to 10% active ingredient. The EXCHANGE™ Herbicide label contains the statement "FOR MANUFACTURING, REFORMULATION AND REPACKAGING AS A HERBICIDE ONLY."

The EXCHANGE™ Herbicide label also has the following addition of Directions for Use "It is a violation of Federal law to use this product in any manner inconsistent with its labeling."

As official notification of the additional product name EXCHANGE™ Herbicide, Monsanto is submitting five (5) final printed 54 gallon drum container labels for the Agency files. Also, a copy of the SHACKLE® C Herbicide label is enclosed for your reference.

If you have any questions or comments concerning this new product name notification, please contact Dr. Kevin Cannon.

Sincerely,

Roy G. Danhaus
Senior Registration Specialist

/dh
Enclosure

cc: K. F. Cannon
G. B. Fuller
L. L. Gingerich
D. L. Gerwitz
K. E. Smith
C. L. Tozer

PRECAUTIONARY STATEMENTS

Hazards to Humans and Domestic Animals

Keep out of reach of children.

WARNING!

CAUSES EYE IRRITATION.
HARMFUL IF SWALLOWED.
MAY CAUSE SKIN IRRITATION.
Do not get in eyes, on skin or on clothing.
Wash thoroughly with soap and water after handling.

FIRST AID: IF IN EYES, immediately flush with plenty of water for at least 15 minutes. Call a physician.

IF ON SKIN, immediately flush with plenty of water. Remove contaminated clothing. Wash clothing before reuse.

IF SWALLOWED, this product will cause gastrointestinal tract irritation. Immediately dilute by swallowing water or milk. Call a physician.

In case of an emergency involving this product, Call Collect, day or night (314) 694-4000.

Environmental Hazards

Do not apply directly to water or wetland (swamps, bogs, marshes or potholes). Do not contaminate water by cleaning of equipment or disposal of wastes.

Physical or Chemical Hazards

Solutions of this product should be mixed and stored only in stainless steel, aluminum, fiberglass, plastic and plastic-lined steel containers.

DO NOT MIX OR STORE THIS PRODUCT OR SOLUTIONS OF THIS PRODUCT IN GALVANIZED STEEL OR UNLINED STEEL (EXCEPT STAINLESS STEEL) CONTAINERS OR SPRAY TANKS.

This product or solutions of this product react with such containers and tanks to produce hydrogen gas which may form a highly combustible gas mixture. This gas mixture could flash or explode, causing serious personal injury, if ignited by open flame, spark, welder's torch, lighted cigarette or other ignition source.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in any manner inconsistent with its labeling.

Storage and Disposal

Do not contaminate water, foodstuffs, seed or feed by storage or disposal.

DISPOSAL:
Wastes resulting from the use of this product that cannot be used or chemically reprocessed should be disposed of in a landfill approved for pesticide disposal or in accordance with applicable Federal, state or local procedures.

Emptied container retains vapor and product residue. Observe all labeled safeguards until container is cleaned, reconditioned or destroyed. DO NOT CUT OR WELD ON OR NEAR THIS CONTAINER.

Do not reuse container. Triple rinse container. Then puncture and dispose of in a sanitary landfill, or by incineration, or, if allowed by state and local authorities, by burning. If burned, stay out of smoke.

FOR MANUFACTURING, REFORMULATION AND REPACKAGING AS A HERBICIDE ONLY.

LIMIT OF WARRANTY AND LIABILITY

This Company warrants that this product conforms to the chemical description on this label. NO OTHER EXPRESS WARRANTY OR IMPLIED WARRANTY OF FITNESS FOR PARTICULAR PURPOSE OR MERCHANTABILITY IS MADE. This warranty is also subject to the conditions and limitations stated herein.

Buyer and all users shall promptly notify this Company of any claims whether based in contract, negligence, strict liability, other tort or otherwise.

Buyer and all users are responsible for all loss or damage from use or handlnig which results from conditions beyond the control of this Company, including, but not limited to, uses or applications in any manner not explicitly set forth in this label or application to or contact with desirable vegetation.

THE EXCLUSIVE REMEDY OF THE USER OR BUYER, AND THE LIMIT OF THE LIABILITY OF THIS COMPANY OR ANY OTHER SELLER FOR ANY AND ALL LOSSES, INJURIES OR DAMAGES RESULTING FROM THE USE OR HANDLING OF THIS PRODUCT (INCLUDING CLAIMS BASED IN CONTRACT, NEGLIGENCE, STRICT LIABILITY, OTHER TORT OR OTHERWISE) SHALL BE THE PURCHASE PRICE PAID BY THE USER OR BUYER FOR THE QUANTITY OF THIS PRODUCT INVOLVED, OR, AT THE ELECTION OF THIS COMPANY OR ANY OTHER SELLER, THE REPLACEMENT OF SUCH QUANTITY, OR, IF NOT ACQUIRED BY PURCHASE, REPLACEMENT OF SUCH QUANTITY. IN NO EVENT SHALL THIS COMPANY OR ANY OTHER SELLER BE LIABLE FOR ANY INCIDENTAL, CONSEQUENTIAL OR SPECIAL DAMAGES.

Buyer and all users are deemed to have accepted the terms of this LIMIT OF WARRANTY AND LIABILITY which may not be varied by any verbal or written agreement.

In case of an emergency involving this product, Call Collect, day or night (314) 694-4000.

MONSANTO COMPANY
AGRICULTURAL PRODUCTS
ST. LOUIS, MISSOURI 63167 U.S.A.

EXCHANGE™

HERBICIDE BY Monsanto

Read the entire label before using this product.

Read "LIMIT OF WARRANTY AND LIABILITY" before buying or using. If terms are not acceptable, return at once unopened.

Keep out of reach of children.

WARNING! Read precautions on side panel.

ACTIVE INGREDIENT:	
*Isopropylamine salt of glyphosate	41.0%
INERT INGREDIENTS:	59.0%
	100.0%

*Contains 480 grams per litre or 4 pounds per U.S. gallon of the active ingredient isopropylamine salt of N-(phosphonomethl)glycine. Equivalent to 356 grams per litre or 3 pounds per U.S. gallon of the acid, glyphosate.

NET 54 U.S. GAL.

EPA Reg. No. 524-339
EPA Est. No. 524-LA-1
MAP-2975/53L

LIMIT OF WARRANTY AND LIABILITY

This Company warrants that this product conforms to the chemical description on this label. NO OTHER EXPRESS WARRANTY OR IMPLIED WARRANTY OF FITNESS FOR PARTICULAR PURPOSE OR MERCHANTABILITY IS MADE. This warranty is also subject to the conditions and limitations stated herein.

Buyer and all users shall promptly notify this Company of any claims whether based in contract, negligence, strict liability, other tort or otherwise.

Buyer and all users are responsible for all loss or damage from use or handling which results from conditions beyond the control of this Company, including, but not limited to, uses or applications in any manner not explicitly set forth in this label or application to or contact with desirable vegetation.

THE EXCLUSIVE REMEDY OF THE USER OR BUYER, AND THE LIMIT OF THE LIABILITY OF THIS COMPANY OR ANY OTHER SELLER FOR ANY AND ALL LOSSES, INJURIES OR DAMAGES RESULTING FROM THE USE OR HANDLING OF THIS PRODUCT (INCLUDING CLAIMS BASED IN CONTRACT, NEGLIGENCE, STRICT LIABILITY, OTHER TORT OR OTHERWISE) SHALL BE THE PURCHASE PRICE PAID BY THE USER OR BUYER FOR THE QUANTITY OF THIS PRODUCT INVOLVED, OR, AT THE ELECTION OF THIS COMPANY OR ANY OTHER SELLER, THE REPLACEMENT OF SUCH QUANTITY, OR, IF NOT ACQUIRED BY PURCHASE, REPLACEMENT OF SUCH QUANTITY. IN NO EVENT SHALL THIS COMPANY OR ANY OTHER SELLER BE LIABLE FOR ANY INCIDENTAL, CONSEQUENTIAL OR SPECIAL DAMAGES.

Buyer and all users are deemed to have accepted the terms of this LIMIT OF WARRANTY AND LIABILITY which may not be varied by any verbal or written agreement.

U.S. Pat. No. 3,799,758 and U.S. Pat. No. 4,405,531 cover use. Other patents are pending.

No license granted under any non-U.S. patent.

*Shackle is a registered trademark of Monsanto Company

MONSANTO COMPANY
AGRICULTURAL PRODUCTS
ST. LOUIS, MISSOURI 63167 U.S.A.

158

MAP-2233.11/53F

PRECAUTIONARY STATEMENTS

Hazards to Humans and Domestic Animals

Keep out of reach of children.

WARNING!

CAUSES EYE IRRITATION.
HARMFUL IF SWALLOWED.
MAY CAUSE SKIN IRRITATION.
Do not get in eyes, on skin or on clothing.
Wash thoroughly after handling.

FIRST AID: IF IN EYES, immediately flush with plenty of water for at least 15 minutes. Call a physician.

IF ON SKIN, immediately flush with plenty of water. Remove contaminated clothing. Wash clothing before reuse.

IF SWALLOWED, this product will cause gastrointestinal tract irritation. Immediately dilute by swallowing water or milk. Call a physician.

In case of an emergency involving this product, Call Collect, day or night (314) 694-4000.

Environmental Hazards

Do not apply directly to water or wetland (swamps, bogs, marshes or potholes). Do not contaminate water by cleaning of equipment or disposal of wastes.

Physical or Chemical Hazards

Solutions of this product should be mixed and stored only in stainless steel, aluminum, fiberglass, plastic and plastic-lined steel containers.

DO NOT MIX OR STORE THIS PRODUCT OR SOLUTIONS OF THIS PRODUCT IN GALVANIZED STEEL OR UNLINED STEEL (EXCEPT STAINLESS STEEL) CONTAINERS OR SPRAY TANKS.

This product or solutions of this product react with such containers and tanks to produce hydrogen gas which may form a highly combustible gas mixture. This gas mixture could flash or explode, causing serious personal injury, if ignited by open flame, spark, welder's torch, lighted cigarette or other ignition source.

Storage and Disposal

Do not contaminate water, foodstuffs, seed or feed by storage or disposal.

DISPOSAL:
Wastes resulting from the use of this product that cannot be used or chemically reprocessed should be disposed of in a landfill approved for pesticide disposal or buried on site in a safe place away from water supplies. All disposal should be in accordance with applicable Federal, state or local procedures.

Emptied container retains vapor and product residue. Observe all labeled safeguards until container is cleaned, reconditioned or destroyed. DO NOT CUT OR WELD ON OR NEAR THIS CONTAINER.

Triple rinse emptied bulk containers. Then offer for recycling or reconditioning, or dispose of in a manner approved by state and local authorities.

CONCENTRATE

SHACKLE® C

HERBICIDE BY Monsanto

For formulation of products (not to exceed 10% active ingredient) for weed and grass control in industrial, residential and ornamental areas.

NOT REVIEWED
In Accordance with PR Notice 82-2.
Based on Draft Labeling Dated RS

It is a violation of Federal law to use this product in any manner inconsistent with its labeling.

Read the entire label before using this product.

Read "LIMIT OF WARRANTY AND LIABILITY" before buying or using. If terms are not acceptable, return at once unopened.

Keep out of reach of children.

WARNING! Read precautions on side panel.

In case of an emergency involving this product, Call Collect, day or night, (314) 694-4000.

ACTIVE INGREDIENT:

*Isopropylamine salt of glyphosate	41.0%
INERT INGREDIENTS:	59.0%
	100.0%

*Contains 480 grams per liter or 4 pounds per U.S. gallon of the active ingredient isopropylamine salt of N-(phosphonomethyl) glycine. Equivalent to 356 grams per liter or 3 pounds per U.S. gallon of the acid, glyphosate.

EPA Reg. No. 524-339

EPA Est. No. 524-NC-1

NET U.S. GAL.

EbU

10· 3·99

Monsanto

Monsanto Company
1101 17th Street, N.W.
Washington, D.C. 20036
Phone: (202) 452-8880

Director
Registration Division (TS767C)
Office of Pesticide Programs
U.S. Environmental Protection Agency
1921 Jefferson Davis Highway
Crystal Mall #2, Room 726
Arlington, Virginia 22202

Attention: Mr. Robert J. Taylor
Product Manager (25)

Subject: Shackle C Herbicide
EPA Reg. No. 524-339

Dear Sir:

As part of an ongoing effort to comply with the data submission requirements of the document "Guidance for the Reregistration of Pesticide Products Containing Glyphosate as the Active Ingredient", Monsanto is submitting five (5) copies of the Shackle C herbicide no weight bulk label. This label has been updated to comply with the labeling requirements described in the registration standard.

If you have any questions regarding this submission, please contact either Kevin Cannon or me.

Sincerely,

Timothy J. Long

Timothy J. Long, Ph.D.
Senior Registration Specialist

cc: KFC

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

Dr. Timothy Long
Monsanto Company
1101 17th Street NW.
Washington, DC 20036

yellow SEP - 7 1988

Dear Dr. Long:

Subject: MON 0139 (Response to Registration Standard)
EPA Registration No. 524-318
MON 0139 (62% Solution)
EPA Registration No. 524-333
Shackle C
EPA Registration No. 524-339
Roundup Herbicide
EPA Registration No. 524-308
Accord Herbicide
EPA Registration No. 524-326
Shackle Herbicide
EPA Registration No. 524-330
Polado Herbicide
EPA Registration No. 524-332
Bronco
EPA Registration No. 524-341
Rodeo Herbicide
EPA Registration No. 524-343
Landmaster Herbicide
EPA Registration No. 524-351
Roundup L&G Herbicide
EPA Registration No. 524-370
Landmaster II
EPA Registration No. 524-376
Ranger Herbicide
EPA Registration No. 524-382
Your Letters Dated November 7 and December 22, 1986;
January 27, March 6, April 10, June 5, and June 8, 1987

The scientific review and evaluation of the information/data submitted above have been completed. The following are our conclusions and comments.

Residue Chemistry

1. We agree that a label restriction for crayfish farming in rice fields will not be necessary once the tolerance for shellfish is established. Until the shellfish tolerance is established, the restriction on double-cropping crayfish in rice fields must remain.

2. Since you have agreed to do the grape processing study and since the processing of both grapes and plums is essentially only a drydown procedure, we defer judgment on the plum processing requirement until the grape processing study is reviewed.

3. We accept the proposed revised labeling for cancellation of specific 24(c) registrations on sorghum/selective equipment and imposing a grazing and feeding restriction for pineapple and sugarcane.

4. Section 180.364(c) of Title 40 of the Code of Federal Regulations (40 CFR 180.364(c)) needs to be completely revised by deleting the existing crop groupings and proposing new groupings that are consistent with 180.34(f) (I through XVIII excluding the herbs and spices crop group XIX). Since field trial residue data are not available for commodities in the herbs and spices crop group, and for other commodities not in a crop group such as those in 180.34(f)(7), i.e., banana, peanuts, mushrooms, etc., field trial residue data are required from the proposed use to support a 40 CFR 180.364(c) tolerance.

5. Based on a previous report showing irrigation waters containing 0.5 and 5X application rates for 3 consecutive days on representative commodities from seven crop groups, the Agency concludes that additional field trial data will not be required for crop group tolerances for the proposed irrigation uses.

6. We conclude that the HPLC glyphosate method is an improvement over the GLC method. It generally gives equal or higher, and more consistent, recoveries. We point out the potential for more positive glyphosate samples and results closer to existing tolerances. Overall data are lacking to show tolerances need to be revised upward. The limit of sensitivity or quantification should be stated as 5 ppb in water and the water limit of detection should be 0.5 ppb.

7. Clean, non-CBI or proprietary (no copyright) methods using the ninhydrin/absorbance detector to enforce food tolerances and the direct injection HPLC revision of these methods to enforce/monitor the 0.5 ppm water tolerance are needed for publication in PAM-II at the same time we publish the MTO, assuming it passes the MTO.

Toxicology

1. Rat Feeding Study

   a. During the discussion, the dose levels were stated to be 1000, 5000, and 20,000 ppm for the rat study. Based on the discussion presented, 20,000 ppm would be consistent with the position paper on maximum tolerated dose (MTD) and the seemingly lack of dose-related effects in the 90-day study.

   b. In the discussion, it was stated by the Agency that a low dose had to be used that would establish the NOEL for the study. The June 5, 1987 Monsanto letter states that the following dose levels have been chosen for the chronic rat study: 0, 2000, 8000, and 20,000 ppm. Please note the Agency has only concurred with the high-dose, not the mid- and low-dose levels.

2. The Agency concurs with the waiver request regarding the acute inhalation study with glyphosate technical. This study is not required.

3. Mouse Oncogenicity Study

   a. The Agency does not concur with the waiver request of the repeat mouse study.

   b. The repeat mouse oncogenicity study is considered to be a specially designed study for the specific purpose of clarifying certain unresolved questions relating to the potential oncogenicity of glyphosate. Therefore, the following recommendations are made:

      1) The study should be performed at dosage levels of 7500, 15,000, and 30,000 ppm.

      2) Only male mice should be tested; 200 mice per group may be needed.

      3) A "tier approach" to the pathological examinations in this study.

         a) First, a very thorough and complete gross necropsy should be performed on all animals in this study, particularly noting all findings suggestive of possible tumors.

         b) Second, a full and complete set of tissues/organs should be excised and fixed from each animal in the study (for possible future need).

c) Third, it will only be necessary in the "first tier" to do the following:

i. Process and examine multiple sections of kidney and liver from all high dosage levels and control animals in the study.

ii. Process and examine all grossly observed "findings" suggestive of possible tumors from all animals in all groups of the study.

4) If the "first tier" examinations do not suggest a potential oncogenic concern, then additional histopathological examinations will not be necessary.

c. A proposed protocol should be submitted to the Agency for comment before the experimental work is initiated.

d. This study is required to be submitted within 50 months from the date of this letter.

Environmental Fate

1. Protocols for Aquatic Dissipation, Forestry, and Irrigated Crops

a. Analytical methods were not included; therefore, a complete assessment cannot be made at this time.

b. Parent compound and the major degradates need to be analyzed.

c. Information noted under Reporting and Evaluation of Data, 164-2, 164-3, 165-3, and 160-5 should be included.

d. The soil and sediment sampling/compositing protocol, and sample storage conditions, should be included for each study.

e. Samples should be taken to sufficient depth to adequately define the extent of leaching.

f. For the aquatic dissipation study, a site representative of a typical rice-growing area should be included.

g. In the irrigated crop study, the sampling of soil at harvest of irrigated crops is not addressed and the referenced field data were not included.

h. In the forestry study, the Instructions for Field Residue Plots (RES-86-GSOP-071-0) were not included.

2. For the photodegradation report FR-258 the spectrum of the light source used should be submitted. This information is required to be submitted within 9 months of the date of this letter.

3. The photodegradation in air is deferred pending the results of the volatility study.

4. The aerobic metabolism study referenced does not fill Guideline requirements. Laboratory experiments should be sufficiently controlled to be able to produce a residue decline curve. The laboratory rate of metabolism is needed as well as the identification of residues. Therefore, an aerobic soil metabolism study must be submitted within 27 months of the date of this letter.

5. When an acceptable anaerobic aquatic metabolism study is submitted, the anaerobic soil metabolism study may be waived.

6. The major problem with the aerobic aquatic metabolism study referenced (MS-0207) was that missing data points as well as the time length was too short to demonstrate the pattern of formation and decline of the degradate MON 0453. Therefore, an aerobic aquatic metabolism study must be submitted 27 months from the date of this letter.

7. No information is available to indicate the study MSL-0207 was carried out under anaerobic conditions. If you have data to support the claim of anaerobic conditions, this information must be submitted within 27 months from the date of this letter. Otherwise, a repeat study must be submitted within the 27 months.

8. Based on the available information, the leaching requirement for glyphosate is satisfied.

9. Copies of the studies cited for the rotational crop accumulation studies and fish accumulation studies should be submitted for review.

10. Field Dissipation

    a. Dissipation of Glyphosate in U.S. Field Soil Following Direct Application of Roundup Herbicide

        1) The portions of this study conducted at the North Dakota (2, 4, and 8 lb ai/A treatments), Illinois (2 and 4 lb ai/A), Indiana (4 and 8 lb ai/A), Ohio (2 lb ai/A), Colorado (sandy loam soil, 4 lb ai/A; loamy sand, 4 and 8 lb ai/A), Texas (2, 4, and 8 lb ai/A); North Carolina (2, 4, and 8 lb ai/A), California (2 lb ai/A), Oklahoma (4 and 8 lb ai/A), Idaho (2 lb ai/A),

Tennessee (2, 4, and 8 lb ai/A), and Kentucky (4 lb ai/A) sites are scientifically sound and provide supplemental information towards the registration of glyphosate.

2) The portions of this study conducted at the Illinois (8 lb ai/A), Colorado (sandy loam, 2 and 8 lb ai/A; loamy sand, 2 lb ai/A), California (4 and 8 lb ai/A), Oklahoma (2 lb/A), Idaho (4 and 8 lb ai/A), Kentucky (2 and 8 lb ai/A), and Florida (2 and 8 lb ai/A) sites are unacceptable because the data were too variable to accurately assess the dissipation of glyphosate in soil.

3) The portions of this study conducted at the Indiana (2 lb ai/A) and Ohio (4 and 8 lb ai/A) sites are unacceptable because insufficient material was present at any sampling interval to establish a residue decline curve.

4) The portion of the study conducted at the Minnesota (2, 4, and 8 lb ai/A) site is unacceptable because of inadequate sampling intervals.

5) Glyphosate (Roundup, test substance not further characterized), at 2, 4, and 8 lb ai/A, dissipated from the upper 6 inches of clay loam (North Dakota, Illinois, Indiana, Ohio), sandy loam (Texas, North Carolina), sandy clay loam (California), loamy sand (Colorado, loam (Oklahoma), silt loam (Idaho, Indiana), and silty clay loam (Kentucky) soils with a half-life of < 64 days. At the Colorado (sandy loam soil) site, the half-life of glyphosate was 194 to 301 days after the application of Roundup at 4 lb ai/A. At all sites by 1 year post-treatment, glyphosate declined in the 0 to 6 inch soil depth from 0.25 to 3.68 ppm to < 0.05 ppm at the 2 lb ai/A rate, 0.11 to 2.3 ppm to < 0.05 to 0.2 ppm at the 4 lb ai/A rate, and 0.52 to 12.6 ppm to < 0.05 to 0.19 ppm at the 8 lb ai/A rate. Maximum concentrations of the primary degradate, aminomethylphosphonic acid (AMPA) were 0.39, 0.58, and 3.07 ppm at the 2, 4, and 8 lb ai/A rates, respectively. In the 6 to 12 inch soil depth, glyphosate concentrations were < 0.17 ppm and AMPA concentrations were < 0.23 ppm. The degradate N-nitrosoglyphosate was not detected (< 0.02 ppm) at any site.

6) This study does not fulfill EPA data requirements for registering pesticides because the test substance was not completely characterized, the test soils were not completely characterized, field test data were not

provided, no pretreatment samples were taken, and no immediate posttreatment samples were taken at Indiana and Ohio sites.

b. Dissipation of Glyphosate in U.S. Field Soils Following Multiple Applications of Roundup Herbicide

1) This study is unacceptable because either the data were too variable to accurately assess the dissipation of glyphosate in soil, or else the sampling intervals were inadequate to establish the half-life of the test substance.

2) This study does not fulfill EPA data requirements for registering pesticides because the test substance was not characterized, the pattern of formation and decline of degradates was not addressed in the orchard soil study, soil characteristics, including textural analysis, were not reported, field test data were not reported, and storage stability data were not reported.

c. Neither of the studies discussed above satisfy data requirements; therefore, field dissipation studies are required within 27 months of the date of this letter.

11. Forestry Dissipation (Roundup Herbicide Dissipation in Cool Climate Forest Soil and Leaf Litter)

a. This study is scientifically sound and provides supplemental information towards the registration of glyphosate.

b. Glyphosate (Roundup, test substance not further characterized) at 1.7 and 3.4 kg/ha, dissipated with a half-life of < 15 days in leaf litter and in the 0 to 6 cm depth of exposed (nonlitter covered) soil. At 344 days posttreatment, < 3.2 percent of the applied glyphosate remained undegraded in the litter and < 10 percent remained undergraded in the soil. In the 7 to 12 cm soil depth, glyphosate ranged from < 0.5 ppm (detection limit) to 2.73 ppm and was independent of treatment rate. AMPA was < 1.17 ppm in the 0 to 6 cm depth of exposed soil and < 0.05 to 2.06 ppm in the litter treated at 1.7 kg/ha, and < 2.34 ppm in the soil and 0.36 to 6.79 in the litter treated at 3.4 kg/ha; maximum AMPA concentrations in the soil were measured on day 344 (final sampling interval).

c. This study does not fulfill the EPA data requirements for registering pesticides because dissipation of glyphosate in the forest canopy, understory, lakes, and streams was not

addressed; the soil and litter were not sampled deep enough to define the extent of leaching and meteorological data were not provided.

d. Since this study does not fulfill requirements, a repeat study must be submitted within 27 months of the date of this letter.

Fish and Wildlife

1. An Evaluation of the Preemergence Herbicidal Activity of CP-70139

   a. The data submitted satisfy the Guidelines 122-1 Seed Germination/Seedling Emergence requirement.

   b. Glyphosate (CP-70139) applied to soil at up to 10.0 lb ai/A caused < 25 percent effect on the spectrum of monocotyledonae and dicotyledonae plants tested.

   c. Testing at the Tier II level for seed germination/seedling emergence is not required.

2. Vegetative Vigor Testing

   a. Since glyphosate is a broad spectrum herbicide affecting grasses and broadleaf weeds, we assume that a > 25 percent detrimental effect would be observed using the maximum label rate on the 10 species recommended in Subdivision J of the Guidelines. For this reason, Tier I, Vegetative Vigor Testing (122-1) will not be required.

   b. To determine the nontoxic, subtoxic (LEC_{50}), and EC_{50} values for glyphosate, Tier II Vegetative Vigor Testing (123-1) will be required. This study is required to be submitted within 9 months of the date of this letter.

Sincerely yours,

Robert J. Taylor VRW
Product Manager (25)
Fungicide-Herbicide Branch
Registration Division (TS-767C)

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

SEP -7 1988

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

Dr. Timothy J. Long
Monsanto Company
1101 17th Street NW.
Washington, DC 20036

yellow copy

Dear Dr. Long:

Subject: MON 0139 (Response to Registration Standard)
EPA Registration No. 524-318
MON 0139 (62% Solution)
EPA Registration No. 524-333
Shackle C
EPA Registration No. 524-339
Roundup Herbicide
EPA Registration No. 524-308
Accord Herbicide
EPA Registration No. 524-326
Shackle Herbicide
EPA Registration No. 524-330
Polado Herbicide
EPA Registration No. 524-332
Bronco
EPA Registration No. 524-341
Rodeo Herbicide
EPA Registration No. 524-343
Landmaster Herbicide
EPA Registration No. 524-351
Roundup L&G Herbicide
EPA Registration No. 524-370
Landmaster II
EPA Registration No. 524-376
Ranger Herbicide
EPA Registration No. 524-382
Your Letters Dated September 3, September 8, September 9, September 10, 1987; February 23, February 24, March 16, April 15, June 20, and July 18, 1988

This acknowledges receipt of the data submitted above in response to the Registration Standard for Glyphosate. The following are a list of studies/information submitted and MRID Numbers assigned the data.

1. Olives and Olive Oil Information

2. Soybean Soapstock Information

3. Peanut Information

4. Tea Information

5. Wheat Milled Products Information

6. Residue Determination of Glyphosate in Laying Hen Tissues and Eggs Following a 28-Day Feeding Study - 405320-01

7. Residue Determination of Glyphosate and AMPA in Swine Tissues Following a 28-Day Feeding Study - 405320-02

8. Residue Determination of Glyphosate and AMPA in Dairy Cow Tissues and Milk Following a 28-Day Feeding Study - 405320-03

9. Storage Stability Study of Glyphosate and AMPA in Swine Tissues, Dairy Cow Tissues and Milk, Laying Hen Tissues and Eggs - 405320-04

10. Metabolism Study of Synthetic $^{13}C/^{14}C$-Labeled Glyphosate and Aminomethylphosphonic Acid in Lactating Goats - 405413-01

11. Metabolism Study of Synthetic $^{13}C/^{14}C$-Labeled Glyphosate and Aminomethylphosphonic Acid in Laying Hens - 405413-02

12. Validation of an Analytical Method for the Determination of Glyphosate Residues in Animal Tissues - 405413-03

13. Glyphosate Residues in Alfalfa Hay and Seed Following Scattered Spot Treatment - 405413-04

14. Irrigated Crop Study - Determination of Glyphosate Residues in Crops, Irrigation Water, Sediment, and Soil Following Treatment of Irrigation Source with Rodeo - 405413-05

15. 90-Day Study of Glyphosate Administered in Feed to Sprague-Dawley Rats - 405594-01

16. Residues in Celery - 405780-01

17. Residues in Spinach - 405780-02

18. Residues in Mango - 405804-01

19. Metabolism of Glyphosate in Sprague-Dawley Rats Part I - 407671-01

20. Metabolism of Glyphosate in Sprague-Dawley Rats Part II - 407671-02

21. Glyphosate Residue in Plums and Prunes Following Preharvest Treatment with Roundup Herbicide - 407853-01

22. Glyphosate Residues in Potatoes and Processed Fractions of Potatoes After Treatment with Roundup Herbicide - 407853-02

23. Glyphosate Residues in Grapes and Grape Processing Commodities Following Directed Spray Treatment with Roundup Herbicide - 407853-03

24. Glyphosate Residues in Sugar Beets and Sugar Beet Processing Commodities Following Preemergent Application of Roundup Herbicide - 407853-04

Sincerely yours,

Robert J. Taylor
Product Manager (25)
Fungicide-Herbicide Branch
Registration Division (TS-767C)

Monsanto

Monsanto Company
1101 17th Street, N.W.
Washington, D.C. 20036
Phone: (202) 452-8880

December 8, 1987

Director
Registration Division (TS767C)
Office of Pesticide Programs
U.S. Environmental Protection Agency
1921 Jefferson Davis Highway
Crystal Mall #2, Room 726
Arlington, Virginia 22202

Attention: Mr. Robert J. Taylor
Product Manager (25)

Subject: Glyphosate Guidance Document
Memorandum of Understanding on
December 2, 1987 EPA/Monsanto Meeting

Dear Sir:

On Wednesday, December 2, 1987, the Environmental Protection Agency and Monsanto personnel met to review and develop clarification on several glyphosate registration standard issues. The attached memorandum outlines what transpired during this meeting, and we are submitting it for your information and file use.

If you have any questions or additions to this memorandum, please contact Lyle Gingerich or me.

Sincerely,

Timothy J. Long

T.J. Long, Ph.D.
Senior Registration Specialist

/bj
cc: L.L. Gingerich

December 2, 1987 Glyphosate Registration Standard Meeting

On Wednesday, December 2, 1987, the following people met at the Environmental Protection Agency offices to review and develop clarification on some glyphosate registration standard questions:

EPA Personnel	Monsanto Personnel
Robert J. Taylor (HFB/Reg. Div.)	Tim Long (St. Louis, MO)
	Tom Armstrong (St. Louis, MO)
	Lyle Gingerich (Washington, DC)

During the discussion, the following comments were developed:

1. Monsanto's November 2, 1987 letter to the Agency requesting postponement of additional protective clothing requirements for glyphosate products has been routed to the Exposure Assessment Branch for review. Based upon comments in our meeting, Monsanto can probably expect a response by mid-December, 1987.

2. Monsanto's October 20, 1987 letter to the Agency requesting deletion of the requirement for chemical resistant aprons and boots for glyphosate products has been routed to the Toxicology Branch for review.

3. Regarding Monsanto's November 5, 1987 submission of nitrosamine analysis data, the Toxicology Branch has reviewed the data and indicated that there are no toxicological concerns. By December 15, 1987 an Agency response to this submission will be expected by Monsanto.

4. Regarding Monsanto's request to change the preharvest interval for the stone fruits group (cherries, peaches, plums, or prunes) from 14 to 17 days, it was agreed that Monsanto should submit a revised label incorporating this change. This will fulfill the registration standard requirement for magnitude of residue data on stone fruits.

5. All preharvest corn and sorghum processing studies will be submitted by Monsanto during the first quarter of 1988 (required submission dates are 2/11/88 and 8/11/88).

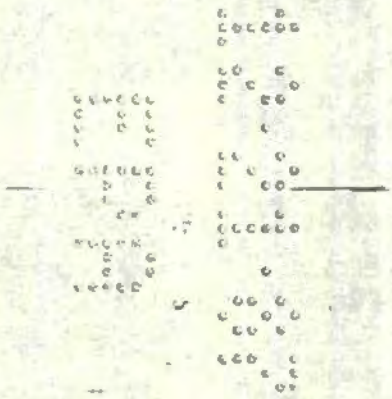
6. Regarding Monsanto's request to amend the preharvest interval for coffee from 14 days to 28 days and to reduce the maximum yearly use rate to 2.0 lbs a.e./acre, it was agreed that Monsanto should submit a revised label incorporating these changes. This will fulfill the registration standard requirement for magnitude of residue data in coffee.

7. On September 8, 1987 Monsanto submitted correspondence to the Agency stating that the spot treatment recommendation for peanuts had been removed from the Roundup label. Furthermore, since preemergence peanut residue data show no detectable glyphosate or AMPA residues, the peanut processing residue data requested in the registration standard should no longer be required. Bob Taylor indicated that this correspondence has been circulated through the Agency for review. Monsanto awaits a response.

8. Monsanto is still awaiting written Agency concurrence on a maximum dose level of 20,000 ppm for the rat oncogenicity study currently being conducted. Please refer to Monsanto's letter of June 8, 1987, and send us your written concurrence.

In conclusion, based upon this meeting, it is Monsanto's understanding that, to date, we are in full compliance with the registration standard submission requirements. For the specific requirements for which we have requested a waiver, the currently listed "Time Frame for Submission" dates in the guidance document are no longer applicable. If (after EPA/Monsanto discussion) the listed data requirements are still deemed necessary, a new time frame for submission of data will be established.

Any comments or additions to this memorandum should be addressed to Lyle Gingerich or Tim Long.



Monsanto

Monsanto Company
1101 17th Street, N.W.
Washington, D.C. 20036
Phone: (202) 452-8880

September 23, 1987

Director
Registration Division (TS767C)
Office of Pesticide Programs
U.S. Environmental Protection Agency
1921 Jefferson Davis Highway
Crystal Mall #2, Room 726
Arlington, Virginia 22202

Attention: Mr. Robert J. Taylor
Product Manager (25)

Subject: Glyphosate Guidance Document
Memorandum of Understanding
on September 18, 1987 EPA/Monsanto
Meeting

Dear Sir:

On Friday, September 18, 1987, the Environmental Protection Agency and Monsanto personnel met to review and develop clarification on some glyphosate registration standard questions. The attached memorandum outlines what transpired during this meeting, and we are submitting it for your information and file use.

If you have any questions or additions to this memorandum, please contact Lyle Gingerich or myself.

Sincerely,

Thomas F. Armstrong
Registration Manager

/yd

Attachment

cc: L. L. Gingerich

SEPTEMBER 18, 1987 GLYPHOSATE REGISTRATION STANDARD MEETING

On Friday, September 18, 1987, the following people met at the Environmental Protection Agency's office to review and develop clarification on some glyphosate registration standard questions:

EPA PERSONNEL	MONSANTO PERSONNEL
Robert Taylor (HFB/Reg. Div.)	Tom Armstrong (St. Louis, MO) Lyle Gingerich (Washington, D.C.)

During the discussion, the following comments were developed:

1. The Agency's glyphosate computer printout that list the status of the glyphosate data requirements is available; however, the list is 6 to 8 months behind on what has really transpired.

2. Submissions since our June 17, 1987 meeting were reviewed. Overall, Monsanto is in full compliance to date; and our future submissions are on schedule.

3. During the first quarter of 1988, the Agency plans to respond to Monsanto's request for the Chronic Mouse Study waiver.

4. For the crops that the Agency has requested a revised Section F, Monsanto may combine the various tolerance requests into one (1) petition and submit one $10,400 fee plus $725 for each raw agricultural commodity on which a tolerance is requested. Thus for the revision of three tolerances, a $12,575 check should be submitted.

5. For the August 28, 1987 Agency letter on "Data Requirements for Alternate Salts of Glyphosate", the word "Filled" means the Agency needs to review the data for the specific crops in question. For those crops or uses that do not involve the cited data gaps, those requested registrations will not be affected by the August 28, 1987 Agency letter.

6. It is our understanding that the Residue Chemistry 171-4 Storage Stability Data Timeline for submission is 18 months (not 15 months as it is incorrectly listed for Product Chemistry 63-17 in the Registration Standard).

In addition to the above comments, it is both the Agency's and Monsanto's understanding that for the specific topics Monsanto has requested a waiver, the currently listed "Time Frame for Submission" dates (in the Glyphosate Guidance Document) are no longer applicable. If (after EPA/Monsanto discussion) the listed data requirements are still necessary, a new time frame for submission dates will be established.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

Mr. Kevin L. Cannon
Monsanto Company
1101 17th Street NW.
Washington, DC 20036

yellow copy

AUG 28 1987

Dear Mr. Cannon:

Subject: Roundup Herbicide (Nontarget Area Aquatic Plant Growth Data)
EPA Registration No. 524-308
MON 0139
EPA Registration No. 524-318
Accord Herbicide
EPA Registration No. 524-326
Shackle Herbicide
EPA Registration No. 524-330
Polado Herbicide
EPA Registration No. 524-332
MON 0139 (62% Solution)
EPA Registration No. 524-333
Shackle C
EPA Registration No. 524-339 ✓
Bronco
EPA Registration No. 524-341
Rodeo Herbicide
EPA Registration No. 524-343
Landmaster Herbicide
EPA Registration No. 524-351
Roundup L&G Herbicide
EPA Registration No. 524-370
Landmaster II
EPA Registration No. 524-376
Ranger Herbicide
EPA Registration No. 524-382
Your Letter Dated June 12, 1987

We have your letter of June 12, 1987 transmitting nontarget area aquatic plant growth data on five aquatic species. Further action will await completion of scientific review and evaluation.

The Master Record Identification Numbers assigned the data are as follows:

Volume I	40236901
Volume II	40236902
Volume III	40236903
Volume IV	40236904
Volume V	40236905
Volume VI	40236906

Sincerely yours,

Robert J. Taylor VKW
Product Manager (25)
Fungicide-Herbicide Branch
Registration Division (TS-767C)

Monsanto Company
1101 17th Street, N.W.
Washington, D.C. 20036
Phone: (202) 452-8880

June 12, 1987

Director
Registration Division (TS767C)
Office of Pesticide Programs
U.S. Environmental Protection Agency
1921 Jefferson Davis Highway
Crystal Mall #2, Room 716D
Arlington, Virginia 22202

Attention: Mr. Robert J. Taylor
Product Manager (25)

Subject: Glyphosate Guidance Document
Submittal of Nontarget Area
Aquatic Plant Growth Data

Dear Sir:

In the glyphosate registration standard (issued August 11, 1986), the Agency requested (on page 89), that Aquatic Plant Growth Data be submitted per §158.150 Nontarget Plants data requirement 122-2 (Tier 1). In compliance with this request, Monsanto is submitting (under separate cover) five (5) volumes (R.D. 779, 780, 781, 782, 783) of data that were developed per guideline 123-2 (Aquatic Plant Growth, Tier 2).

According to Subdivision J, Nontarget Plants guideline (page 40) portions of Tier 1 (§122-2) test may be combined with the respective parts of the Tier 2 test (§123-2) and performed as one test; therefore, our Monsanto glyphosate data have been developed and submitted per the 123-2 requirements.

The Tier 2 test include the following five (5) aquatic species:

- Selenastastrum capricornutum
- Navicula pelliculosa
- Skeletonema costatum
- Anabaena flos-aquae
- Lemna gibba

We request the Agency assign MRID numbers to the submissions and notify Monsanto of these numbers. If you have any questions concerning this submission, please contact Lyle Gingerich or myself.

Sincerely

Thomas F. Armstrong
Registration Manager

Attachment

cc: L. L. Gingerich

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

AUG 28 1987

Mr. Kevin L. Cannon
Monsanto Company
1101 17th Street NW.
Washington, DC 20036

Dear Mr. Cannon:

Subject: MON 0139 62% Solution (Memorandum of Understanding Rat Feeding Study)
EPA Registration No. 524-333
MON 0139
EPA Registration No. 524-318
Shackle C
EPA Registration No. 524-339
Your Letter Dated June 8, 1987

We have your letter of June 8, 1987 transmitting a memorandum of understanding confirming a high dose level for the 2-year rat feeding study. The memorandum has been routed to the proper discipline for comment.

Sincerely yours,

Robert J. Taylor
Product Manager (25)
Fungicide-Herbicide Branch
Registration Division (TS-767C)

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

Mr. Kevin L. Cannon
Monsanto Company
1101 17th Street NW.
Washington, DC 20036

yellow copy

AUG 28 1987

Dear Mr. Cannon:

Subject: Roundup Herbicide (Citrus Fruit Residue Information)
EPA Registration No. 524-308
MON 0139
EPA Registration No. 524-318
Accord Herbicide
EPA Registration No. 524-326
Shackle Herbicide
EPA Registration No. 524-330
Polado Herbicide
EPA Registration No. 524-332
MON 0139 (62% Solution)
EPA Registration No. 524-333
Shackle C
EPA Registration No. 524-339
Bronco
EPA Registration No. 524-341
Rodeo Herbicide
EPA Registration No. 524-343
Landmaster Herbicide
EPA Registration No. 524-351
Roundup L&G Herbicide
EPA Registration No. 524-370
Landmaster II
EPA Registration No. 524-376
Ranger Herbicide
EPA Registration No. 524-382
Your Letter Dated April 10, 1987

The scientific review and evaluation of the subject data have been completed. The following are our comments/conclusions.

1. The calculations to derive whole fruit residues in PP#6G1734 have been satisfactorily clarified.

2. The residue data submitted in PP#6G1734 are adequate to support the citrus fruits group tolerance.

3. The established tolerance of 0.2 ppm for citrus is adequate.

4. The established feed additive tolerance of 0.4 ppm for dried citrus pulp is now considered inadequate. The registrant should submit a feed additive petition proposing that the level be increased to 1.0 ppm, based on available data in PP#6G1734.

5. Concentration of residues has been shown to occur in citrus molasses. A feed additive tolerance of 1.0 ppm should be proposed the processing fraction, citrus molasses at 1.0 ppm.

Further action will await proposal of the requested feed additive tolerances.

Sincerely yours,

Robert J. Taylor RJW
Product Manager (25)
Fungicide-Herbicide Branch
Registration Division (TS-767C)

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

AUG 28 1987

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

Mr. Kevin L. Cannon
Monsanto Company
1101 17th Street NW.
Washington, DC 20036

yellow copy

Dear Mr. Cannon:

Subject: Roundup Herbicide (Reconsideration of Worker Safety Rules)
EPA Registration No. 524-308
MON 0139
EPA Registration No. 524-318
Accord Herbicide
EPA Registration No. 524-326
Shackle Herbicide
EPA Registration No. 524-330
Polado Herbicide
EPA Registration No. 524-332
MON 0139 (62% Solution)
EPA Registration No. 524-333
Shackle C
EPA Registration No. 524-339
Bronco
EPA Registration No. 524-341
Rodeo Herbicide
EPA Registration No. 524-343
Landmaster Herbicide
EPA Registration No. 524-351
Roundup L&G Herbicide
EPA Registration No. 524-370
Landmaster II
EPA Registration No. 524-376
Ranger Herbicide
EPA Registration No. 524-382
Your Letter Dated February 9, 1987

The scientific review and evaluation of the information submitted above have been completed. The following are our comments/conclusions.

1. Based on some of the acute toxicology studies on file and poisoning incidences reported for glyphosate use in California, the Agency concludes that some formulations of glyphosate are eye irritants and possibly skin irritants.

2. To clarify some of the possible confusion in the Registration Standard in regard to worker safety rules, the following statements are required for nonhome use products.

   a. The following statements are required for all glyphosate products that contain the signal word "WARNING" based on either dermal irritation or eye irritation.

      Keep all unprotected persons, children, livestock, and pets away from treated areas or where there is danger of drift.

      Do not rub eyes with hands. See First Aid (Practical Treatment) Section.

      HANDLE THE CONCENTRATE ONLY WHEN WEARING THE FOLLOWING PROTECTIVE CLOTHING AND EQUIPMENT.

      Wear chemical resistant gloves, chemical resistant apron, chemical resistant shoes, shoe coverings, or boots, long sleeve shirt, long legged pants, and a face shield or goggles.

      WEAR THE FOLLOWING PROTECTIVE CLOTHING DURING APPLICATION, EQUIPMENT REPAIR, CLEANING, DISPOSAL OF THE SPRAY SOLUTION, AND DURING REENTRY TO TREATED AREAS BEFORE THE SPRAY HAS DRIED.

      Wear long sleeved shirt, long legged pants, chemical resistant gloves, and a face shield or goggles. A helmet with visor may be worn during open cockpit aerial application.

      Only during application from a tractor with a completely enclosed cab or aerially with an enclosed cockpit will the face shield or goggles and gloves not be required. Chemical resistant gloves must be available in the cab or cockpit and must be worn while exiting.

      IMPORTANT! Before removing gloves, wash them with soap and water. Always wash hands, face and arms with soap and water before smoking, eating, drinking, or toileting.

AFTER WORK, wash protective clothing and equipment with soap and water after each use. Personal clothing worn during use should be laundered separately from household articles. Clothing or protective equipment heavily contaminated or drenched with glyphosate must be disposed of in accordance with State or local regulations.

HEAVILY CONTAMINATED OR DRENCHED CLOTHING CANNOT BE ADEQUATELY DECONTAMINATED.

b. The following Worker Safety Rules are required for all glyphosate products intended for agricultural uses and containing the signal word "CAUTION."

Keep all unprotected persons, children, livestock, and pets away from treated areas or where there is danger of drift.

When handling this product wear chemical resistant gloves, long sleeve shirt, and long legged pants.

Before removing gloves, wash them with soap and water. Always wash hands, face, and arms with soap and water before smoking, eating, drinking, or toileting.

After work: Wash clothing and gloves with soap and water after each use. Personal clothing worn during use should be laundered separately from household articles. Clothing or protective equipment heavily contaminated or drenched with glyphosate must be disposed of in accordance with State or local regulations. Heavily contaminated or drenched clothing cannot be adequately decontaminated.

Sincerely yours,

Robert J. Taylor VKW
Product Manager (25)
Fungicide-Herbicide Branch
Registration Division (TS-767C)

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

Mr. Kevin L. Cannon
Monsanto Company
1101 17th Street NW.
Washington, DC 20036

Dear Mr. Cannon:

Subject: MON 0139 62% Solution (Review of Processing Protocols)
EPA Registration No. 524-333
MON 0139
EPA Registration No. 524-318
Shackle C
EPA Registration No. 524-339
Your Letter Dated December 22, 1986

The scientific review and evaluation of the processing protocols submitted above have been completed. The following are our conclusions/ comments.

I. GRAPE PROCESSING PROTOCOL

The following deficiencies are noted.

- No information is provided on storage of samples. Documentation of storage procedures/conditions and adequate (concurrent) frozen storage stability data are needed to validate the integrity of residues in experimental samples.

- No information is provided on the processing procedure itself. You are advised to follow standard/accepted commercial processing procedures or, if the processing is done on a laboratory scale, to simulate actual commercial practice as closely as possible. Details of the processing procedure followed should be included as part of the petitioner's study report.

- No information is provided on the analytical methodology to be used for determining residues. You are advised to use accepted enforcement methods, appropriately validated.

II. THE PRUNE PROCESSING PROTOCOL

The same deficiencies as stated in the grape processing protocol apply for this protocol.

III. POTATO PROCESSING PROTOCOL

In addition to deficiencies stated for the grape processing protocol, the following deficiency exists for the potato processing study.

- o Processed potato waste is now recognized as an animal feed item. Potato waste is defined as "wet or dried potato pulp, wet or dry potato peel, or a mixture of these commodities." Feed additive tolerances for pesticide residues should be established in or on "processed potato waste" using the maximum reported level in/on cull potatoes, granules, wet peel, and dry peel.

IV. SUGAR BEET PROCESSING PROTOCOL

The same deficiencies as stated for the grape processing study apply for this protocol.

V. ALFALFA PROCESSING PROTOCOL

Deficiencies 1 and 3 stated for the grape processing study apply for this protocol.

Provided the above studies are conducted properly and result in measurable weathered residues in the raw agricultural commodities, they should provide the processing data needed to determine the need, if any, for food/feed additive tolerances on these commodities and to satisfy the identified data gaps (note the additional requirement now being imposed by this letter to provide wet and dry potato peel data). A final judgment of adequacy will await review of the actual studies.

Please note these studies are due X months (see Table A of Registration Standard) from the date of issuance of the Standard.

Comments on other protocols submitted with these will follow once the scientific review and evaluation are completed.

Sincerely yours,

Robert J. Taylor RJT
Product Manager (25)
Fungicide-Herbicide Branch
Registration Division (TS-767C)

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

Mr. Kevin L. Cannon
Monsanto Company
1101 17th Street NW.
Washington, DC 20036

Dear Mr. Cannon:

Subject: MON 0139 (Confirmation of Dosages for Rat Metabolism Study)
EPA Registration No. 524-318
~~Shackle Herbicide~~ MON 0139 (62% Solution)
EPA Registration No. ~~524-330~~ 524-333
Shackle C Herbicide
EPA Registration No. 524-339
Your Letter Dated November 10, 1986

AUG 28 1987

The scientific review and evaluation of the letter submitted above have been completed. We concur that the high dose level of glyphosate in the rat metabolism study should be 1 g/kg.

Sincerely yours,

Robert J. Taylor
Product Manager (25)
Fungicide-Herbicide Branch
Registration Division (TS-767C)

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

AUG 14 1987

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: Glyphosate - Glyphosate Rat Metabolism Study - Response to Monsanto's Letter Regarding High-Dose Level - EPA Registration No. 524-333

Caswell No. 661A
Record No. 197280
Proj. No. 7-0803

FROM: William Dykstra
Toxicology Branch
Hazard Evaluation Division (TS-769C)

William Dykstra 7/31/87

TO: Robert Taylor, PM 25
Fungicide-Herbicide Branch
Registration Division (TS-767C)

THRU: Edwin Budd, Section Head
Toxicology Branch
Hazard Evaluation Division (TS-769C)

Budd 8/12/87

8/14/87

Action Requested

Respond to Monsanto's letter regarding high-dose level for glyphosate in rat metabolism study.

Conclusions and Recommendations

Toxicology Branch (TB) concurs that the high-dose level of glyphosate in the rat metabolism study should be 1 g/kg. This dose level was agreed upon by Monsanto and TB (see letter of November 10, 1986 from T.J. Long of Monsanto to R. Taylor, RD/OPP; attached) by previous telephone communications.

Review - No new toxicity data were submitted.

Attachment

Monsanto

MONSANTO AGRICULTURAL COMPANY
800 N. Lindbergh Boulevard
St. Louis, Missouri 63167
Phone (314) 694-1000

November 10, 1986

Director
Registration Division (TS767C)
Office of Pesticide Programs
U.S. Environmental Protection Agency
1921 Jefferson Davis Highway
Crystal Mall #2, Room 716D
Arlington, Virginia 22202

Attention: Mr. Robert J. Taylor
Product Manager (25)

Subject: Glyphosate Rat Metabolism Study
• Response Requested

Dear Sir:

In Monsanto's response to the EPA "Guidance Document on the Reregistration of Pesticide Products Containing Glyphosate" submitted on November 7, 1986 it was stated that we would comply with the requirement to submit a new rat metabolism study. During the development of a protocol for this study, a question was raised regarding how high the high dosage level needed to be for a relatively non-toxic material such as glyphosate. Based upon the following rationale, it is Monsanto's opinion that a high dosage level of 1 gram per kilogram of body weight (1 g/kg) is sufficient to achieve the purposes of a general metabolism study. We request the Agency's concurrence on this issue.

The EPA FIFRA Pesticide Assessment Guidelines (November, 1984) state that "The upper dose should produce toxic or pharmacologic signs, but not produce severe effects or a high incidence of mortality which would prevent a meaningful evaluation." When glyphosate is administered in single oral doses, it is not possible to elicit signs of toxicity in the absence of high mortality. A review of the results of the acute oral toxicity study in rats with glyphosate (BD-77-428; EPA Accession No. 241301) confirms this statement. At dosage levels which do not elicit a high percent mortality, no significant effects on body weight gain or physical signs of toxicity are observed. Significant signs of toxicity (i.e. ataxia, tremors, etc.) are only sporadically observed at high dosage levels which kill the majority of exposed animals.

F.C

Glyphosate Rat Metabolism Study

With these results in mind, if one refers again to the FIFRA testing guidelines for a 90-day subchronic feeding study, it is stated that if no toxicity is observed in a limit test at 1 gram/kg, further testing is not normally required. Furthermore, the Agency's 1986 "Position Paper on Maximum Tolerated Dose in Oncogenicity Studies" states that in oncogenicity studies, a dose of 1 gram/kg body weight per day should provide an adequate upper limit for testing. Since one of the purposes of a metabolism study is to aid in the interpretation of results of these long-term animal studies, dosage levels above 1 gram/kg should not be necessary for relatively non-toxic materials such as glyphosate.

Finally, due to the limited aqueous solubility of glyphosate (1.2%), administration of dosages greater than 1 gram/kg in distilled water or saline would not be technically feasible. Even at a dosage of 1 gram/kg it will be necessary to buffer the dosing solution to pH 7 in order to increase the solubility of glyphosate to a degree which will enable maintaining dosing volumes within acceptable limits.

On November 5, 1986 I spoke with the Agency's Bill Dysktra regarding this issue. Dr. Dysktra agreed that, based upon our discussion, a high dosage level of 1 gram/kg for the rat metabolism study should be adequate. He suggested confirming this with Ted Farber. Therefore, on November 10, 1986 I discussed our rationale with Dr. Farber. He agreed that a high dosage level of 1 gram/kg would be sufficient. He requested that I document our conversation in writing to you.

I would appreciate receiving your concurrence on the agreement reached between myself and Drs. Farber and Dykstra as soon as possible. If you would like to discuss this issue further, please feel free to call me at (314)694-8851.

Sincerely,

Timothy J. Long

Timothy J. Long, Ph.D.
Product Toxicology Specialist

/jb

bcc: T.F. Armstrong
E.E. Debus
T.W. Fuhremann
L.L. Gingerich
R.L. Harness
F.S. Serdy

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

Mr. Kevin F. Cannon
Monsanto Company
1101 17th Street NW.
Washington, DC 20036

yellow

Dear Mr. Cannon:

Subject: Roundup Herbicide (Citrus Fruits Residue Information)
EPA Registration No. 524-308
MON 0139, EPA Registration No. 524-318
Accord Herbicide, EPA Registration No. 524-326
Shackle Herbicide, EPA Registration No. 524-330
Polado Herbicide, EPA Registration No. 524-332
MON-0139 (62% Solution), EPA Registration No. 524-333
Shackle C, EPA Registration No. 524-339
Bronco, EPA Registration No. 524-341
Rodeo Herbicide, EPA Registration No. 524-343
Landmaster Herbicide, EPA Registration No. 524-351
Roundup L&G Herbicide, EPA Registration No. 524-370
Landmaster II, EPA Registration No. 524-376
Ranger Herbicide, EPA Registration No. 524-392
Your Letter Dated April 10, 1987

We have your letter of April 10, 1987, transmitting citrus fruits residue information in support of the subject registrations. Further action will await completion of scientific review and evaluation.

The Master Record Identification (MRID) Number assigned this information is 40159401.

Sincerely yours,

Robert J. Taylor VKW
Product Manager (25)
Fungicide-Herbicide Branch
Registration Division (TS-767C)

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

JUN 24 1987

Mr. Kevin F. Cannon
Monsanto Company
1101 17th Street NW.
Washington, DC 20036

Dear Mr. Cannon:

Subject: Roundup Herbicide (Seed Germination/Seedling Emergence Study)
EPA Registration No. 524-308
MON 0139, EPA Registration No. 524-318
Accord Herbicide, EPA Registration No. 524-326
Shackle Herbicide, EPA Registration No. 524-330
Polado Herbicide, EPA Registration No. 524-332
MON-0139 (62% Solution), EPA Registration No. 524-333
Shackle C, EPA Registration No. 524-339
Bronco, EPA Registration No. 524-341
Rodeo Herbicide, EPA Registration No. 524-343
Landmaster Herbicide, EPA Registration No. 524-351
Roundup L&G Herbicide, EPA Registration No. 524-370
Landmaster II, EPA Registration No. 524-376
Ranger Herbicide, EPA Registration No. 524-382
Your Letter Dated April 10, 1987

We have your letter of April 10, 1987, transmitting Plant Protection data (Seed Germination/Seedling Emergence) in support of the subject registrations. Further action will await completion of scientific review and evaluation.

The Master Record Identification (MRID) Number assigned this study is 40159301.

Sincerely yours,

Robert J. Taylor
Product Manager (25)
Fungicide-Herbicide Branch
Registration Division (TS-767C)

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

Mr. Kevin F. Cannon
Monsanto Company
1101 17th Street NW.
Washington, DC 20036

yellow

JUN 24 1987

Dear Mr. Cannon:

Subject: Roundup Herbicide (Request Deletion of Vegetative Vigor Requirement)
EPA Registration No. 524-308
MON 0139, EPA Registration No. 524-318
Accord Herbicide, EPA Registration No. 524-326
Shackle Herbicide, EPA Registration No. 524-330
Polado Herbicide, EPA Registration No. 524-332
MON-0139 (62% Solution), EPA Registration No. 524-333
Shackle C, EPA Registration No. 524-339
Bronco, EPA Registration No. 524-341
Rodeo Herbicide, EPA Registration No. 524-343
Landmaster Herbicide, EPA Registration No. 524-351
Roundup L&G Herbicide, EPA Registration No. 524-370
Landmaster II, EPA Registration No. 524-376
Ranger Herbicide, EPA Registration No. 524-382
Your Letter Dated March 6, 1987

We have your letter of March 6, 1987 transmitting a request for deletion of the Vegetative Vigor Requirement. Further action will await completion of scientific review and evaluation.

Sincerely yours,

Robert J. Taylor VKW
Product Manager (25)
Fungicide-Herbicide Branch
Registration Division (TS-767C)

Monsanto

Monsanto Company
1101 17th Street, N.W.
Washington, D.C. 20036
Phone: (202) 452-8880

March 6, 1987

Director
Registration Division (TS767C)
Office of Pesticide Programs
U. S. Environmental Protection Agency
1921 Jefferson Davis Highway
Crystal Mall #2, Room 716D
Arlington, Virginia 22202

Attention: Mr. Robert J. Taylor
Product Manager (25)

Subject: Amended Comments to
Glyphosate Guidance Document,
- Request deletion of §158.150 Plant Protection, 122-1 Vegetative Vigor Data Requirement

Roundup® Herbicide
EPA Registration No. 524-308
Shackle® Herbicide
EPA Registration No. 524-330
Shackle C® Herbicide
EPA Registration No. 524-339
Polado® Herbicide
EPA Registration No. 524-332
Rodeo® Herbicide
EPA Registration No. 524-343
Roundup L&G® Herbicide
EPA Registration No. 524-370
Landmaster® Herbicide
EPA Registration No. 524-351
Landmaster II® Herbicide
EPA Registration No. 524-376
MON-0139 (62% solution)
EPA Registration No. 524-333
Ranger® Herbicide
EPA Registration No. 524-382

Dear Sir:

Roundup® herbicide (EPA Reg. No. 524-308) is a glyphosate formulation, and it has been registered by the Agency since 1974. In addition, various other glyphosate herbicide formulations are also registered by the Agency. Glyphosate herbicides control most actively growing herbaceous plants, including many emerged annual and perennial grasses and broadleaf weeds.

As part of the reregistration process, the glyphosate Guidance Document (issued August 11, 1986) requested the following §158.150 Plant Protection, Subdivision J (Nontarget Plants) data be developed:

122-1	seed germination/seedling emergence
122-1	vegetative vigor
122-2	aquatic plant growth

Per the completion date listed in the glyphosate Guidance Document (pages 89 and 90), Monsanto plans to submit to the Agency the 122-1 seed germination/seedling emergence and 122-2 aquatic plant growth data. However, since glyphosate herbicides control most emerged annual and perennial grasses and broadleaf weeds and the approved glyphosate herbicide labels already provide adequate precautionary labeling or other statements to minimize the potential adverse effects to nontarget plants, it would be redundant and unnecessary for Monsanto to conduct the Agency requested 122-1 vegetative vigor studies that are designed to determine if glyphosate applications will cause abnormal symptoms in herbaceous seedlings.

For your reference, attached are Agency approved Roundup® herbicide and Rodeo® herbicide label segments that have nontarget plant precautionary labeling statements highlighted in yellow.

Since glyphosate herbicides labels already contain nontarget plant precautionary labeling statements, glyphosate herbicides control most emerged annual and perennial weeds and it would be redundant for Monsanto to conduct the requested 122-1 vegetative vigor studies, Monsanto is now amending our submitted November 7, 1986 glyphosate Guidance Document compliance comments by requesting Agency approval to delete the 122-1 vegetative vigor data requirement. This amendment request is a follow-up to the February 1987 discussion that Mr. Lyle Gingerich and yourself had concerning the 122-1 vegetative vigor data requirement.

If you have questions about this glyphosate Guidance Document deletion request, please contact Lyle Gingerich or myself.

Sincerely,

Thomas Armstrong

Thomas F. Armstrong
Registration Manager

/jjs

Enclosures
cc: L. L. Gingerich

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

Mr. Kevin F. Cannon
Monsanto Company
1101 17th Street NW.
Washington, DC 20036

JUN 24 1987

Dear Mr. Cannon:

Subject: Roundup Herbicide (Request to Delete Worker Safety Rules from Label)
EPA Registration No. 524-308
MON 0139, EPA Registration No. 524-318
Accord Herbicide, EPA Registration No. 524-326
Shackle Herbicide, EPA Registration No. 524-330
Polado Herbicide, EPA Registration No. 524-332
MON-0139 (62% Solution), EPA Registration No. 524-333
Shackle C, EPA Registration No. 524-339
Bronco, EPA Registration No. 524-341
Rodeo Herbicide, EPA Registration No. 524-343
Landmaster Herbicide, EPA Registration No. 524-351
Roundup L&G Herbicide, EPA Registration No. 524-370
Landmaster II, EPA Registration No. 524-376
Ranger Herbicide, EPA Registration No. 524-382
Your Letter Dated February 9, 1987

We have your letter of February 9, 1987, transmitting a report entitled "Irritation, Sensitization, Photoirritation, and Photosensitization Assays with Glyphosate Herbicide" in support of a request to delete the worker safety rules labeling. Further action will await completion of scientific review and evaluation.

The Master Record Identification (MRID) Number assigned this study is 40085601.

Sincerely yours,

Robert J. Taylor
Product Manager (25)
Fungicide-Herbicide Branch
Registration Division (TS-767C)

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

Mr. Kevin F. Cannon
Monsanto Company
1101 17th Street NW.
Washington, DC 20036

JUN 24 1987

Dear Mr. Cannon:

Subject: Roundup Herbicide (Additional Information on Mouse Oncogenicity Study)
EPA Registration No. 524-308
MON 0139, EPA Registration No. 524-318
Accord Herbicide, EPA Registration No. 524-326
Shackle Herbicide, EPA Registration No. 524-330
Polado Herbicide, EPA Registration No. 524-332
MON-0139 (62% Solution), EPA Registration No. 524-333
Shackle C, EPA Registration No. 524-339
Bronco, EPA Registration No. 524-341
Rodeo Herbicide, EPA Registration No. 524-343
Landmaster Herbicide, EPA Registration No. 524-351
Roundup L&G Herbicide, EPA Registration No. 524-370
Landmaster II, EPA Registration No. 524-376
Ranger Herbicide, EPA Registration No. 524-382
Your Letter Dated January 27, 1987

We have your letter of January 27, 1987, transmitting additional information on the mouse oncogenicity study. Further action will await completion of scientific review and evaluation.

Sincerely yours,

Robert J. Taylor
Product Manager (25)
Fungicide-Herbicide Branch
Registration Division (TS-767C)

Monsanto

Monsanto Company
1101 17th Street, N.W.
Washington, D.C. 20036
Phone: (202) 452-8860

January 27, 1987

Director
Registration Division (TS767C)
Office of Pesticide Programs
U. S. Environmental Protection Agency
1921 Jefferson Davis Highway
Crystal Mall #2, Room 716D
Arlington, Virginia 22202

Attention: Mr. Robert J. Taylor
Product Manager (25)

Subject: Glyphosate Guidance Document,
Additional Information to Support
Roundup® Herbicide
EPA Registration No. 524-308
Shackle® Herbicide
EPA Registration No. 524-330
Shackle C® Herbicide
EPA Registration No. 524-339
Polado® Herbicide
EPA Registration No. 524-332
Rodeo® Herbicide
EPA Registration No. 524-343
Roundup L&G® Herbicide
EPA Registration No. 524-370
Landmaster® Herbicide
EPA Registration No. 524-351
Landmaster II® Herbicide
EPA Registration No. 524-376
MON-0139 (62% solution)
EPA Registration No. 524-333
Ranger® Herbicide
EPA Registration No. 524-382

Dear Sir:

On August 9, 1983, Monsanto submitted to the Agency an eight (8) volume report entitled "A Chronic Feeding Study of Glyphosate in Mice". The accession numbers 251007 - 251014 were assigned to this submission.

In the glyphosate registration standard (issued August 11, 1986), the Agency requested the glyphosate oncogenicity study in mice be repeated. The Agency stated glyphosate produced an equivocal oncogenic response in the mouse; and the SAP determined that the oncogenic potential of glyphosate could not be determined from existing data and proposed that the study be repeated in order to clarify these equivocal findings (refer to pages 6, 7 and 81 of the glyphosate guidance document).

Monsanto firmly believes that glyphosate is not an oncogen, and we therefore do not agree with the position taken by the Agency. We believe that all of the data on file with the Agency clearly show that glyphosate does not exhibit any treatment related oncogenic effects.

Monsanto has compiled information that totally supports its position on glyphosate. In addition to Monsanto's own evaluation, this matter has been reviewed by various United States independent experts. The unanimous conclusion reached by these scientists is that there is no treatment-related oncogenic effect from glyphosate in the chronic mouse study as questioned by EPA. The independent expert's conclusion were submitted to the Agency on January 23, 1986 as part of Monsanto's glyphosate comments for the February 11, 1986 SAP meeting, and independent expert's conclusions were also submitted November 7, 1986 as part of Monsanto's comments to the Glyphosate Guidance Document.

The purpose of this submission is to offer additional expert information which further supports our conclusion that glyphosate is not oncogenic in mice.

Monsanto is now submitting pages 30, 31 and 32 of the FAO (Food and Agriculture Organization) Plant Production and Protection Paper #77, (dated January 27, 1987) a report covering the 1986 Joint Meeting on Pesticide Residues (JMPR) in Rome. The JMPR is a joint meeting of the FAO and the World Health Organization (WHO). The purpose of this meeting is to establish maximum residue levels (MRL's) for agricultural chemicals involved in international trade. The unanimous conclusion of this WHO panel was that there was no evidence of an oncogenic effect in the chronic mouse study.

This report from the JMPR, plus all of the other expert opinions available to the Agency, provides conclusive evidence that the subject mouse study does not exhibit any treatment related oncogenic effects. Hence, we request that the Agency do the following:

A. Conclude that the mouse oncogenicity study conducted with glyphosate exhibits no treatment related oncogenic effects.

B. Accept this subject study as being adequate and fulfilling all guideline requirements and delete the requirement in the registration standard that it be repeated.

C. Reclassify glyphosate as demonstrating no oncogenic effects and place it into Class E of the oncogenic rating system.

Should you have any questions concerning the JMPR report, we would suggest that you contact the international experts who prepared this report. Should you have any questions concerning this request, please feel free to contact us at Monsanto. Please inform us of the MRID number assigned to this document.

Sincerely,

Thomas Armstrong

Thomas F. Armstrong
Registration Manager

Enclosure

cc: L. L. Gingerich

/jjs

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

JUN 24 1987

Mr. Kevin F. Cannon
Monsanto Company
1101 17th Street NW.
Washington, DC 20036

Dear Mr. Cannon:

Subject: MON 0139 62% Solution (Protocols for Several Studies)
EPA Registration No. 524-333
MON 0139
EPA Registration No. 524-318
Shackle C
EPA Registration No. 524-339
Your Letter Dated December 22, 1986

We have your letter of December 22, 1986, transmitting protocols for several required studies. Further action will await completion of scientific review and evaluation.

Sincerely yours,

Robert J. Taylor
Product Manager (25)
Fungicide-Herbicide Branch
Registration Division (TS-767C)

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

JUN 24 1987

Mr. Kevin F. Cannon
Monsanto Company
1101 17th Street NW.
Washington, DC 20036

Dear Mr. Cannon:

Subject: Roundup Herbicide (Soil Dissipation)
EPA Registration No. 524-308
MON 0139, EPA Registration No. 524-318
Accord Herbicide, EPA Registration No. 524-326
Shackle Herbicide, EPA Registration No. 524-330
Polado Herbicide, EPA Registration No. 524-332
MON-0139 (62% Solution), EPA Registration No. 524-333
Shackle C, EPA Registration No. 524-339
Bronco, EPA Registration No. 524-341
Rodeo Herbicide, EPA Registration No. 524-343
Landmaster Herbicide, EPA Registration No. 524-351
Roundup L&G Herbicide, EPA Registration No. 524-370
Landmaster II, EPA Registration No. 524-376
Ranger Herbicide, EPA Registration No. 524-382
Your Letters Dated August 6 and August 7, 1986

We have your letters of August 6 and August 7, 1986, transmitting soil dissipation information in support of the subject herbicides. Further action will await completion of scientific review and evaluation. The Accession Numbers assigned the data are as follows:

Direct Application to Soil	264332
Forest Soils and Multiple Applications	264343

Sincerely yours,

Robert J. Taylor
Product Manager (25)
Fungicide-Herbicide Branch
Registration Division (TS-767C)

Monsanto

Monsanto Company
1101 17th Street, N.W.
Washington, D.C. 20036
Phone: (202) 452-8880

August 6, 1986

Director
Registration Division (TS767C)
Office of Pesticide Programs
U. S. Environmental Protection Agency
1921 Jefferson Davis Highway
Crystal Mall #2, Room 716D
Arlington, Virginia 22202

Attention: Mr. Robert J. Taylor
Product Manager (25)

Subject: Roundup® Herbicide
EPA Reg. No. 524-308
Glyphosate Soil Dissipation Information
• Direct Application to Soil

Dear Sir:

Roundup herbicide has been registered by the Agency since 1974. Monsanto is continually conducting research on Roundup. As a result of these research efforts, Monsanto is submitting for your file use, the "Dissipation of Glyphosate In U.S. Field Soils Following Direct Applications of Roundup® Herbicide" study (R.D. No. 696).

These data show the average half-life for dissipation of glyphosate in U.S. field soils is generally six (6) weeks or less, and the average time required for dissipation of 90% of the observed initial glyphosate in soils is less than four (4) months.

We request that the Agency let us know the accession number under which this submission is filed. If you have questions or comments about this submission, please contact Lyle Gingerich or myself.

Sincerely,

Tom Armstrong

Thomas F. Armstrong
Registration Manager

/pt
Enclosures

cc: L. L. Gingerich

Monsanto

Monsanto Company
1101 17th Street, N.W. ,
Washington, D.C. 20036
Phone: (202) 452-8680

August 7, 1986

Director
Registration Division (TS767C)
Office of Pesticide Programs
U. S. Environmental Protection Agency
1921 Jefferson Davis Highway
Crystal Mall #2, Room 716D
Arlington, Virginia 22202

Attention: Mr. Robert J. Taylor
Product Manager (25)

Subject: Roundup® Herbicide
EPA Reg. No. 524-308
Glyphosate Soil Dissipation Information
- Forest Soils
- Multiple Applications

Dear Sir:

Roundup herbicide has been registered by the Agency since 1974. Monsanto is continually conducting research on Roundup. As a result of these research efforts, Monsanto is submitting for your file use, the following two (2) soil dissipation studies (R.D. No. 697) as additional data to support our Roundup registration:

1. Roundup® Herbicide Dissipation In Cool Climate Forest Soil and Leaf Litter (MSL-2950)

2. Dissipation of Glyphosate In U.S. Field Soils Following Multiple Application of Roundup® Herbicide (MSL-3352).

We request that the Agency let us know the accession number under which this submission is filed. If you have questions or comments about this submission, please contact Lyle Gingerich or myself.

Sincerely,

Tom Armstrong

Thomas F. Armstrong
Registration Manager

/pt
Enclosures

cc: L. L. Gingerich

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

Monsanto Compay
1101 17th Street NW.
Washington, DC 20036

yellow copy

DEC 18 1986

Attention: Kevin F. Cannon

Gentlemen:

Subject: Roundup Herbicide (Product Chemistry Data)
EPA Registration No. 524-308
Rodeo Herbicide
EPA Registration No. 524-343
MON 0139
EPA Registration No. 524-318
MON 0139 62% Solution
EPA Registration No. 524-333
Shackle C
EPA Registration No. 524-339 ✓
Shackle
EPA Registration No. 524-330
CP 70139
EPA Registration No. 524-326
Roundup L&G
EPA Registration No. 524-370
Your Letter Dated June 30, 1986

We have your letter of June 30, 1986 transmitting product chemistry data in support of the subject registrations. Further action will await completion of scientific review and evaluation.

The Accession Number assigned this volume of data is 263795.

Sincerely yours,

Robert J. Taylor 1/6 W
Product Manager (25)
Fungicide-Herbicide Branch
Registration Division (TS-767C)

25

Monsanto

Monsanto Company
1101 17th Street, N.W.
Washington, D.C. 20036
Phone: (202) 452-8880

June 30, 1986

Director
Registration Division (TS767C)
Office of Pesticide Programs
U. S. Environmental Protection Agency
1921 Jefferson Davis Highway
Crystal Mall #2, Room 716D
Arlington, Virginia 22202

Attention: Mr. Robert J. Taylor
Product Manager (25)

Subject: Roundup® Herbicide
EPA Reg. Nos. 524-308,
524-330, 524-332, 524-339,
524-343, 524-351, 524-370
Submission of Additional
Glyphosate and Roundup
Product Chemistry Data.

Dear Sir:

At this time, Monsanto Company submits the "PRODUCT CHEMISTRY DATA TO SUPPORT THE CONTINUED REGISTRATION OF GLYPHOSATE (N-PHOSPHONOMETHYLGLYCINE)" study and "PRODUCT CHEMISTRY DATA TO SUPPORT REGISTRATION OF MON-2139 (ROUNDUP® HERBICIDE), A FORMULATION OF N-PHOSPHONOMETHYLGLYCINE IN THE FORM OF ITS ISO-PROPYLAMINE SALT" study as additional product chemistry data.

These studies comply with the Agency's October 1982 Pesticide Assessment Guidelines Subdivision D - Product Chemistry, and these data support Roundup®, Shackle®, Shackle® C, Landmaster®, Roundup® L & G, Rodeo®, and Polado® Plant Growth Regulator herbicides' registrations.

Please inform me of the accession number assigned to this submission. If you have any questions about this submission, please contact Lyle Gingerich or me.

Sincerely,

Tom Armstrong

Thomas F. Armstrong
Registration Manager

/pt
Enclosures

cc: L. L. Gingerich

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

Monsanto Compay
1101 17th Street NW.
Washington, DC 20036

yellow cpy DEC 18 1986

Attention: Kevin F. Cannon

Gentlemen:

Subject: Roundup Herbicide (PAM Residue Method for Glyphosate and AMPA Analysis)
EPA Registration No. 524-308
Rodeo Herbicide
EPA Registration No. 524-343
MON 0139
EPA Registration No. 524-318
MON 0139 62% Solution
EPA Registration No. 524-333
Shackle C
EPA Registration No. 524-339 ✓
Shackle
EPA Registration No. 524-330
CP 70139
EPA Registration No. 524-326
Roundup L&G
EPA Registration No. 524-370
Your Letter Dated May 19, 1986

We have your letter of May 19, 1986 transmitting a residue method for glyphosate and AMPA analysis in support of the subject registrations. Further action will await completion of scientific review and evaluation.

The Accession Number assigned this volume of data is 262896.

Sincerely yours,

Robert J. Taylor RJW
Product Manager (25)
Fungicide-Herbicide Branch
Registration Division (TS-767C)

25

Monsanto

Monsanto Company
1101 17th Street, N.W.
Washington, D.C. 20036
Phone: (202) 452-8880

May 19, 1986

Director
Registration Division (TS767C)
Office of Pesticide Programs
U. S. Environmental Protection Agency
1921 Jefferson Davis Highway
Crystal Mall #2, Room 716D
Arlington, Virginia 22202

Attention: Mr. Robert J. Taylor
Product Manager (25)

Subject: PAM Residue Method for glyphosate and AMPA analysis

Dear Sir:

Roundup® herbicide is registered by the Agency for use in many cropping systems. The currently approved GLC method of analysis was developed in 1972.

Since 1972, technology has advanced significantly; and Monsanto has developed a residue method for analysis of glyphosate and aminomethylphosphonic acid (AMPA). This HPLC method for analysis (1) reduces the analysis time to approximately one-half (1/2) of the current time required to complete the GLC analysis, (2) has better analytical recovery (greater than 70%), and (3) the HPLC method is an easier procedure for the analyst to follow.

To validate the HPLC residue method, Monsanto selected five different matrixes: alfalfa, cabbage, grapes, soybeans, and water. The results of this analysis are contained in the enclosed May 19, 1986 petition (R.D. No. 677, Special Report MSL-5677).

Since the new HPLC residue method has significant advantages over the current GLC method, Monsanto requests Agency approval to use the new method to support our glyphosate residue analysis. This new HPLC method of analysis is contained on pages 77-95 of Part A in the enclosed petition. Monsanto also gives permission for this HPLC method to be made available in PAM for enforcement purposes.

If you have any questions on this submission, please contact Lyle Gingerich or myself.

Sincerely,

Tom Armstrong

Thomas F. Armstrong
Registration Manager

/pt
Enclosures

cc: L. L. Gingerich

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

DEC 18 1986

Monsanto Compay
1101 17th Street NW.
Washington, DC 20036

yellow copy

Attention: Kevin F. Cannon

Gentlemen:

Subject: Roundup Herbicide (Add Information For One-Year Dog Study)
EPA Registration No. 524-308
Rodeo Herbicide
EPA Registration No. 524-343
MON 0139
EPA Registration No. 524-333
Shackle C
EPA Registration No. 524-339
Shackle
EPA Registration No. 524-330
CP 70139
EPA Registration No. 524-326
Roundup L&G
EPA Registration No. 524-370
Your Letter Dated August 11, 1986

We have your letter of August 11, 1986 transmitting additional information on the 1-year dog feeding study. Further action will await completion of scientific review and evaluation.

The Accession Number assigned this volume of data is 264334.

Sincerely yours,

VCW

Robert J. Taylor
Product Manager (25)
Fungicide-Herbicide Branch
Registration Division (TS-767C)

Monsanto

Monsanto Company
1101 17th Street, N.W.
Washington, D.C. 20036
Phone: (202) 452-8880

August 11, 1986

Director
Registration Division (TS767C)
Office of Pesticide Programs
U. S. Environmental Protection Agency
1921 Jefferson Davis Highway
Crystal Mall #2, Room 716D
Arlington, Virginia 22202

Attention: Mr. Robert J. Taylor
Product Manager (25)

Subject: Roundup® Herbicide, Rodeo Herbicide, Landmaster® Herbicide, Shackle® Herbicide, Shackle® C Herbicide, and Polado® Plant Growth Regulator; EPA Reg. Nos. 524-308, 524-330, 524-351, 524-339, 524-332, 524-343.

Addendum to One-Year Toxicology Study in Dogs with Glyphosate.

Dear Sir:

On May 28, 1986, the Agency reported that based on the scientific review and evaluation of the glyphosate one-year dog study (accession number 260021), the subject study was classified as Guideline data.

At this time, Monsanto submits for your information an addendum to the one-year toxicology study in dogs with glyphosate. This addendum contains Monsanto's response to the questions raised by the Agency in its May 28, 1986 letter regarding pituitary weights in the referenced study. The overall conclusion is that the apparent decreases in pituitary weights observed for mid and high dose male dogs were not related to glyphosate administration, but they were attributable to a higher than usual mean control group pituitary weight.

Please inform us of the accession number assigned to this submission. If you have further questions about this submission, please contact Lyle Gingerich or myself.

Sincerely,

Thomas F. Armstrong
Registration Manager

/pt
Enclosures

cc: L. L. Gingerich

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

Mr. Kevin F. Cannon
Monsanto Company
1101 17th Street NW.
Washington, DC 20036

JUN 24 1987

Dear Mr. Cannon:

Subject: Roundup Herbicide (Reanalysis of Water, Cotton, Soybeans, Pasture Grasses, and Alfalfa)
EPA Registration No. 524-308
MON 0139, EPA Registration No. 524-318
Accord Herbicide, EPA Registration No. 524-326
Shackle Herbicide, EPA Registration No. 524-330
Polado Herbicide, EPA Registration No. 524-332
MON-0139 (62% Solution), EPA Registration No. 524-333
Shackle C, EPA Registration No. 524-339
Bronco, EPA Registration No. 524-341
Rodeo Herbicide, EPA Registration No. 524-343
Landmaster Herbicide, EPA Registration No. 524-351
Roundup L&G Herbicide, EPA Registration No. 524-370
Landmaster II, EPA Registration No. 524-376
Ranger Herbicide, EPA Registration No. 524-392
Your Letter Dated October 14, 1986

We have your letter of October 14, 1986, transmitting a study entitled "Reanalysis of Water, Cotton, Soybeans, Pasture Grasses, Alfalfa and other Legumes for Glyphosate and Aminomethylphosphonic Acid" in support of the subject registrations. Further action will await completion of scientific review and evaluation.

The Accession Number assigned the data is 262896.

Sincerely yours,

Robert J. Taylor
Product Manager (25)
Fungicide-Herbicide Branch
Registration Division (TS-767C)

Herb - Fung.

Monsanto

Monsanto Company
1101 17th Street, N.W.
Washington, D.C. 20036
Phone: (202) 452-8880

October 14, 1986

Director
Registration Division (TS767C)
Office of Pesticide Programs
U. S. Environmental Protection Agency
1921 Jefferson Davis Highway
Crystal Mall #2, Room 716D
Arlington, Virginia 22202

Attention: Mr. Robert J. Taylor
Product Manager (25)

524-339

Subject: Roundup® Herbicide
EPA Reg. No. 524-308
Reanalysis of Water, Cotton, Soybeans, Pasture Grasses, Alfalfa and other Legumes for Glyphosate and Aminomethylphosphonic Acid

Dear Sir:

262896

Roundup® herbicide has been registered by the Agency since 1974. Monsanto is submitting for your files one research report entitled "Reanalysis of Water, Cotton, Soybeans, Pasture Grasses, Alfalfa and other Legumes for Glyphosate and Aminomethlyphosphonic Acid", study R.D. No. 707. This report represents current research to update the registration status of Roundup.

The enclosed report contains a comparison of residue analysis methods. The current gas-liquid chromatographic (GLC) residue method is compared to high-pressure liquid chromatography (HPLC) for the detection of glyphosate and aminomethylphosphonic acid residues in various crops and water.

We request that the Agency let us know the accession number under which this submission is filed. If you have questions or comments about this submission please contact Lyle Gingerich or myself.

Sincerely,

Kevin F. Cannon/jjs

Kevin F. Cannon
Senior Registration Specialist

cc: L. L. Gingerich
/jjs

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

Mr. Kevin F. Cannon
Monsanto Company
1101 17th Street NW.
Washington, DC 20036

yellow JUN 24 1987

Dear Mr. Cannon:

Subject: Roundup Herbicide (90-Day Response and Forms)
EPA Registration No. 524-308
MON 0139, EPA Registration No. 524-318
Accord Herbicide, EPA Registration No. 524-326
Shackle Herbicide, EPA Registration No. 524-330
Polado Herbicide, EPA Registration No. 524-332
MON-0139 (62% Solution), EPA Registration No. 524-333
Shackle C, EPA Registration No. 524-339
Bronco, EPA Registration No. 524-341
Rodeo Herbicide, EPA Registration No. 524-343
Landmaster Herbicide, EPA Registration No. 524-351
Roundup L & G Herbicide, EPA Registration No. 524-370
Landmaster II, EPA Registration No. 524-376
Ranger Herbicide, EPA Registration No. 524-382
Your Letter of November 7, 1986

We have your submission of November 7, 1986, transmitting comments on the Standard and other 90-day requirements for the subject products. The submitted Confidential Statements of Formula and FIFRA section 3(c)(2)(B) summary sheets have been added to the files.

Further action will await completion of scientific review and evaluation.

Sincerely yours,

Robert J. Taylor RJT
Product Manager (25)
Fungicide-Herbicide Branch
Registration Division (TS-767C)

Monsanto

Monsanto Company
1101 17th Street, N.W.
Washington, D.C. 20036
Phone: (202) 452-8880

November 7, 1986

Director
Registration Division (TS767C)
Office of Pesticide Programs
U. S. Environmental Protection Agency
1921 Jefferson Davis Highway
Crystal Mall #2, Room 716D
Arlington, Virginia 22202

Attention: Mr. Robert J. Taylor
Product Manager (25)

Subject: Comments to Glyphosate Guidance Document
Received August 11, 1986

524-339

Dear Sir:

On August 11, 1986 the EPA issued the Guidance Document (dated June 30, 1986) for the reregistration of pesticide products containing glyphosate. Monsanto is now replying to this document.

Our response is divided into seven parts, and they are the following:

PART	TOPICS
A.	Completed FIFRA Section 3(c)(2)(B) Summary Sheets
B.	Completed Confidential Statement of Formulas
C.	Detailed comments to the Guidance Document
D.	Comments on the chronic mouse study
E.	Comments on the environmental fate studies
F.	Comments on the Worker Safety Rules
G.	Comments on Table A requirements

We believe this information places us in full compliance to date with this document. If we have inadvertently missed anything please contact us immediately.

When the Agency reviews the enclosed information, Monsanto anticipates that the Agency will concur with Monsanto's comments. If the Agency does not concur, we assume that you will respond in adequate time for Monsanto to complete any required studies.

Thank you for your consideration of these replies and requests. Should you have any questions, please feel free to contact us. Please inform us of the accession number assigned to our comment document.

Sincerely,

Thomas Armstrong

Thomas F. Armstrong
Registration Manager

Attachments
cc: L. L. Gingerich
/jjs

COMMENTS IN REPLY TO THE GUIDANCE DOCUMENT FOR THE REREGISTRATION OF PESTICIDE PRODUCTS CONTAINING GLYPHOSATE AS THE ACTIVE INGREDIENT Dated June 30, 1986 and Issued August 11, 1986

R.D. No. 710

November 7, 1986

Report Compiled by:
T. F. Armstrong

MONSANTO AGRICULTURAL COMPANY
800 NORTH LINDBERGH BOULEVARD • ST. LOUIS • MISSOURI • 63167

DISTRIBUTION

1. U. S. Environmental Protection Agency, Washington, D. C.
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5. W. D. Carpenter
6. R. L. Harness
7. G. B. Fuller
8. J. A. Miles
9. W. W. Withers
10. St. Louis Registration
11. St. Louis Registration
12. St. Louis Registration

As per the requirement on page 45 of this Guidance Document, Confidential Statements of Formula for the following products are included in this section:

Roundup® herbicide ✓

Rodeo® herbicide ✓

Roundup® L&G herbicide ✓

Shackle® herbicide ✓

Shackle® C herbicide ✓

MON 0139 Technical Solution (53.5%) 524-318

CP-70139 524-326

MON 0139 (62% Solution) ✓

Bronco® herbicide 524-341

Landmaster® herbicide 524-351

Landmaster® II herbicide 524-376

Ranger® herbicide 524-382

Polado® Plant Growth Regulator ✓

Chemicals Covered By This Standard, Page 4
Part A - Description of Chemicals

The common name for Polado® is listed as the sodium salt of glyphosate, the correct common name should be sodium sesqui salt of glyphosate.

The trade names Roundup®, Rodeo®, Roundup® L&G, Shackle® and Shackle® C are described on page 4 as the trade names for isopropylamine salt of glyphosate. However, this list is not complete. In addition to these, the following glyphosate products also are registered by the Agency:

PRODUCTS	REGISTRATION NUMBER
MON 0139 Technical Solution (53.5%)	524-318
CP-70139	524-326
MON 0139 (62% Solution)	524-333
Bronco®	524-341
Landmaster®	524-351
Landmaster® II	524-376
Ranger®	524-382

We request that the Agency include these corrections in the glyphosate Guidance Document.

III Agency Assessment, Page 5
Summary Science Statement

Based upon the most recent acute data (BD-77-428; Accession No. 241301) the acute oral, acute dermal and primary skin irritation categories for technical glyphosate should all be IV, not III for oral and dermal as stated. The eye irritation category is correctly listed as III. Please correct this.

III Agency Assessment, Page 5
Toxicology Characteristics

Acute Toxicity - EPA states that acute inhalation and dermal sensitization studies have not been submitted and are required. A dermal sensitization study in guinea pigs (BD-83-008) has previously been submitted to the Agency, and the Agency has accepted, (July 29, 1985), this as a core-minimum study. There appears to be no justification for an acute inhalation study with glyphosate because a) People are not exposed to glyphosate. If any exposure does occur, it is either to the isopropylamine or sodium sesqui salts of glyphosate. Adequate inhalation toxicity studies have been or are being conducted with these end use materials. The results of the available studies indicate a relatively low degree of acute inhalation toxicity. b) Glyphosate is a non-volatile solid material which is handled in manufacture [redacted] which precludes any inhalation exposure. We therefore request the Agency concur with Monsanto's opinion that this acute inhalation study is not required per Section 158.135, 81-3 Guideline since glyphosate is not an inhalable material.

Page 6 - Paragraph 1

The Agency states that "Glyphosate produced an equivocal oncogenic response in the mouse, causing a slight increase in the incidence of renal tubular ademonas..." This is clearly a presumption by the EPA that the tumors were compound-related. Such a presumption cannot be supported by equivocal data, and it was not supported by the Scientific Advisory Panel findings. Quoting the SAP report, "...no oncogenic effect is demonstrated using concurrent controls" and "...the level of concern raised by historical control data was not great enough to displace putting primary emphasis on the concurrent controls." Therefore, we request the Agency to delete the following statement in the Glyphosate Guidance Document: "causing a slight increase in the incidence of renal tubular adenomas".

Page 6 - Paragraph 1

The statement "These examinations revealed ...additional sections" is misleading in that it implies the control group tumor was not really present. A more accurate wording of this section would be the following:

> These examinations revealed no additional tumors, but confirmed the presence of the tumors identified in the original study report, and one tumor in the control group. After examination of the slides the Agency concluded that this lesion did not represent a pathophysiologically significant change.

We request the Agency accept this alternate language.

Page 6 - Paragraph 3

The principal reason for the SAP classifying glyphosate as a "Class D" as stated in this paragraph ignores the tremendous importance of the concurrent control group tumor. A more accurate wording would be "The principal reason for this assessment by the SAP was their determination that, after adjusting for the greater survival in the high dose mice compared to the concurrent controls, and considering the presence of one tumor in the concurrent control group, no statistically significant differences existed". We request the Agency accept this alternate language.

Page 7 - Paragraph 1

The Agency requests a repeat of the chronic feeding/oncogenicity study in mice to fully address the questions of "... whether the apparent effects noted in the mouse study [renal tubular adenomas] are biologically relevant." The results of the mouse bioassay do not provide positive, or even suggestive, evidence of carcinogenicity. The most that can be said is that the results were equivocal as, in fact, the Scientific Advisory Panel stated. Furthermore, the SAP pointed out the fact that this equivocal finding occurred only at a dose level that exceeded the MTD. Quoting from the SAP report, "... no oncogenic effect is demonstrated using concurrent controls" and"... the level of concern raised by historical control data was not great enough to displace putting primary emphasis on the concurrent controls." There appears to be no justification for requiring the repeat of a study with equivocal findings at single site, only at dosage levels exceeding tbe MTD.

Several expert toxicologists intimately familiar with the glyphosate chronic/oncogenic mouse study results, and personally involved in the SAP hearing on this issue, were asked to evaluate the need for a repeat study. All experts agreed that additional testing is not justified since the current study was conducted at levels exceeding the MTD and failed to demonstrate a treatment-related oncogenic effect. Their evaluations are enclosed. (see Part D).

As discussed in the next comment topic, the fact that Monsanto has agreed to repeat the chronic/oncogenic rat study with glyphosate diminishes even further the justification for a repeat mouse study. As pointed out by Dr. Farber at the SAP hearing, "If in fact there wasn't a remaining MTD issue in regard to the rat study, and the rat was run at a somewhat higher level and nothing was seen, then basically the whole thing comes out as no evidence of carcinogenicity." The results of the current rat and mouse studies, along with results to be obtained from a repeat rat study, should be sufficient to assess the oncogenic potential of glyphosate. A repeat mouse study is not necessary.

Finally, based upon a review of the principles expressed in the Agency's draft "Position Paper on Maximum Tolerated Dose (MTD) in Oncogenicity Studies", it is clear that the chronic/oncogenic mouse study was conducted at dosage levels which greatly exceeded the upper limit of 7,000 ppm required for mouse studies. Furthermore, none of the requirements listed in that document which would necessitate a repeat study are fulfilled for the mouse study (see Attachment 1, in part D). We request the Agency concur with Monsanto that the study is not required.

Page 8 - Paragraph 1

The Agency states that a repeat rat oncogenicity study is required in which the highest dosage tested is an MTD. Monsanto agrees to repeat this study. A 90-day subchronic rat study is scheduled to start in November, 1986. Based upon the principles stated in the Agency's draft "Position Paper on Maximum Tolerated Dose (MTD) in Oncogenicity Studies," the dosage levels for the 90-day study will be 1,000, 5,000, and 20,000 ppm glyphosate in the diet. Before starting the oncogenicity study, dosage levels will be determined in consultation with the Agency.

Page 8 - Paragraph 2

In the discussion of the 1-year chronic feeding study in dogs, it should be pointed out that the high dosage level of 500 mg/kg/day was the maximum level achievable based upon a consideration of the maximum size and number of gelatin capsules which could reasonably be administered daily to a dog for one year.

In regard to the pituitary weight changes referred to in this paragraph, on August 11, 1986 Monsanto submitted an "Addendum to One-Year Toxicology Study in Dogs with Glyphosate" (RD 698) which addressed these issues. The overall conclusion was that there was no evidence tbat the decreased pituitary weights observed in mid and high dose males could be attributed to glyphosate administration, and that, based upon historical control data, the apparent decreases were more likely the result of an unusually high mean pituitary weight for the concurrent control males.

Metabolism
Pages 10 and 11

The Agency has requested that Monsanto repeat the general metabolism studies. Monsanto agrees to conduct and submit these required studies as listed in our response to this Guidance Document (Part G). Based on the comments from pages 10 and 11 of the Guidance Document it is Monsanto's understanding that the toxicology branch has reviewed the following two reports: (1) The Gross Metabolism of N-phosphonomethyl Glycine-^{14}C in the Laboratory Rat Following a Single Dose. Monsanto Report Number 297; EPA Reg. No. 524-308; MRID #00108098. (2) The Dynamics of Accumulation and Depletion of Orally Ingested N-phosphonomethyl Glycine-^{14}C; Monsanto Report Number 309; EPA Reg. No. 524-308; MRID #00108116. We mention this since on Table A, page 82 under section on Special Testing, no bibliographic citation are given.

One of the deficiencies cited (under Method number 2) was that excreta were not analyzed for the presence of metabolites. Monsanto believes sufficient data are available and the Agency's request to repeat this specific deficiency be dropped. The data on the analysis of excreta from the study described in the two reports reviewed by the Toxicology Branch (as cited above) was presented in the following report:

> Moran, S., Colvin, L.; Rueppel, M.; et al (1973). Final Report on CP 67573 Residue and Metabolism: Part 12: The Isolation and Identification of the Metabolites of CP 67573-^{14}C Excreted by the Laboratory Rat; Monsanto Report Number 306, MRID #108101.

N-Nitroso-Glyphosate
Page 11 - Paragraph 3

The Agency states that N-nitroso-glyphosate (NNG) is in category III based upon acute oral toxicity data. Based upon the acute oral toxicity data submitted to the Agency (Y-76-122; Accession No. 229785), the acute oral LD_{50} is 7600 mg/kg. This would put NNG into category IV, not III, for oral toxicity. We request this discrepancy be corrected.

Page 11 - Paragraph 5

In addition to the 90-day subchronic oral toxicity study in rats with NNG mentioned in this paragraph (no NOEL established; LEL 3,000 mg/kg/day) a second 90-day study in rats (PRL-78-22; Accession No. 238823) was submitted to the Agency. In this study, no evidence of subchronic toxicity was observed up to the maximum dosage tested of 2000 mg/kg/day.

A 90-day subchronic oral toxicity study in mice (IR-77-222; Accession No. 238823) was also submitted to the Agency. In this study, evidence of subchronic toxicity was observed at the highest level tested - 500 mg/kg/day. The NOEL was considered to be 150 mg/kg/day. We request that reference to these additional studies be included in the Glyphosate Guidance Document

Page 12 - Paragraph 1

The Agency states that no acceptable studies for mutagenicity are available for NNG. Reverse mutation assays in Salmonella typhimurium and Saccharomyces cerevisiae have been submitted to the Agency (BIO-76-116; Accession No. 229785). NNG was not mutagenic in either of these systems. We request this discrepancy be corrected. The available data indicates that NNG present as a trace contaminate in glyphosate is not a toxicological concern.

The Agency notes that the glyphosate metabolite (AMPA) is formed on plants in amounts that can range as high as 28% of the total residue. The Agency further notes that since the metabolism is not adequately understood, this metabolite may pose a hazard to humans. Monsanto does not agree with this statement since exposure to this metabolite by humans is both infrequent and at low levels.

First, we would state that AMPA is a soil metabolite and not believed to be formed in growing plants. Low levels could be formed if residues were on the surface of the plant or during plant senescense if high levels were present. When formed, it is transient in nature as it rapidly degrades to natural products.

The majority of the glyphosate used is applied either as a preplant or directed spray to the base of perennial plants. Residues of either glyphosate or AMPA are rarely detected as a result of these types of applications. When detected the levels are always in the ppb range.

One would likewise not expect humans to be exposed to significant amounts of AMPA via drinking water. While low levels of glyphosate can be detected soon after application to potable water, levels of AMPA are usually approximately two fold lower and again transient in nature.

This metabolite has been detected at low levels in forages treated topically with glyphosate. However, animal product residue studies show that this metabolite is not expected to transfer from the feed to edible portions of the animal.

The last application method to be considered is preharvest application for weed control. This is presently registered for use on cotton where no AMPA was detected in cotton seed. A petition is pending which would allow such applications to soybeans. Residues of both glyphosate and AMPA are detected following this type of application to soybeans. Levels of AMPA can be present in ppm levels in the RAC but are still not considered to be a source of significant exposure for the following reasons.

Following approval by EPA, we expect this use to be limited, and should not exceed a few percentage of the total acreage grown. It will only be used on those fields with significant weed problems at harvest. It is not detected in soybean oil which represents 93% of the total amount of soybeans consumed by people. Finally, it can be present in soybean meal at levels somewhat lower than the RAC; however, soybean meal has a rather low contribution to the human diet.

Therefore, human exposure to the glyphosate metabolite AMPA probably does not occur to the majority of the population; and when it does occur, it is generally at very low levels. Hence this metabolite should not be considered to be of concern.

Physiological and Biochemical Behavior Characteristics
Page 13 - Paragraph 5

Additional metabolism studies with ruminants and poultry are required by the Agency. Monsanto will agree to conduct and submit the required studies as listed in this Guidance Document.

Environmental Characteristics,
Page 13, paragraph 6 and Page 14, paragraph 1

EPA states "Glyphosate and aminomethylphosphonic acid dissipation rates and concentrations in treated forest soils are extremely variable ranging from < 0.002 ppm in streamwater samples to 89 ppm in foliage samples."

We would like to suggest that the last word on page 13 (soils) be deleted, and replaced with the word "sites". This then make the remainder of this paragraph correct. We would also add that as detailed in the following two paragraphs, when residues are present in forest sites, they rapidly decline.

For stream water samples, (EPA Accession # 246006) the glyphosate concentration peaked at 0.27 ppm on the day of application; then it declined to <0.002 ppm (below the analytical detection limit) by the fourth day and remained at that low level for all subsequent samples.

The 89 ppm glyphosate concentration was detected in the shrub foliage sampled on the day of application (EPA Accession #246658). By days 3, 7, 14, 28 and 55 after application, glyphosate concentration (ppm) were 9.3, 5.7, 1.1, 0.6 and 0.18 ppm, respectively.

Page 14 - Paragraph 1

The Agency states that "Glyphosate has the potential to contaminate surface waters because of application to aquatic sites." The use of the word "contaminate" is misleading because Rodeo, is approved by the Agency for use in and around aquatic sites for weed control and an action level of 0.5 ppm in water has been established. Therefore, we request the word contaminate be replaced with the term "be present in".

Page 14 - Paragraph 2

The Agency states that for the environmental fate studies, only the hydrolysis study is acceptable to fulfill Guideline requirements. Specifically, the Agency has determined that no data or insufficient data are available regarding photodegradation, laboratory soil and aquatic metabolism, mobility and confined rotational crops.

Since, based on our review, it appears that adequate data are available to fulfill these guideline requirements, Monsanto strongly maintains that these conclusions are incorrect. A substantial number of study

reports have been submitted to the Agency for the purpose of supporting glyphosate registration, but were not included in the bibliography, plus very few of the large number of public literature references which contain data pertinent to these issues were considered in reaching the stated conclusion.

Monsanto maintains that there are sufficient data readily available to satisfy the majority of the requirements which were judged to be inadequately met in the registration standard. The evidence from all of these studies clearly demonstrate that glyphosate presents no potential of harm to the environment because it is rapidly and irreversibly bound to the soil or sediment, making it largely unavailable to other living systems, and that microbial metabolism or photodegradation converted glyphosate to only one significant transient metabolite prior to complete mineralization.

When the Agency reviews the cited data in Part E of this response, Monsanto anticipates that the Agency will concur with Monsanto that these studies are not required.

Exposure
Page 14 - Paragraph 3

EPA states "Application from aircraft increases the potential exposure of humans and nontarget organisms to glyphosate due to spray drift and volatilization."

Glyphosate's vapour pressure as listed in the Monsanto petition submitted to the Agency on June 30, 1986, is "practically zero". Thus glyphosate is not expected to volatilize, and this sentence should be changed to read, "Application from aircraft increases the potential exposure of humans and nontarget organisms to glyphosate due to spray drift."

Exposure
Page 14 - Paragraph 4

The Agency states "to reduce the risk of injury to skin and eyes from the use of glyphosate, the Agency is requiring that worker safety rules requiring protective clothing appear on all formulated products labeled for agriculture or aquatic use". We first note that the formulation labelled for use in and around aquatic sites does not contain a surfactant and the results of acute toxicity studies place the formulation in category IV (ODES). Therefore, this formulation (Rodeo) should not be subject to these worker safety rules.

Second, we maintain that all other formulations of glyphosate are presently adequately labelled according to the results of the acute toxicity studies and the labelling guidelines. Hence, the requirement for the worker safety rules and protective clothing should not be required.

To justify the need for these worker safety rules, The Agency references the California Department of Food and Agriculture (CDFA) reports ranking glyphosate third in the number of illnesses reported from exposure to pesticides. Monsanto has obtained these published CDFA reports for the four year period 1982-1985 and we have thoroughly analyzed them. This review indicates that a total of 245 exposures were reported during the four year reporting period. However, only 144 (58.8%) of these exposures were judged by CDFA to have a definite or probable likelihood of actually causing the reported illness; 98 (68.1%) of these 144 exposures involved exposure to the eyes, 38 (26.4%) were exposures to the skin. Eye exposures were primarily to individuals mixing, loading and applying the product. In tbe four year period only 6 incidences of skin exposure to mixers or loaders were reported. Of greater significance, little or no data is provided indicating the severity of reported illnesses. No reports of hospitalization are contained in the listing for glyphosate exposure. Therefore, these reports which are factually and scientifically deficient, are invalid for drawing any conclusions and the reference by the EPA should be deleted. Finally, we are not aware of any of these incidents reported were validated as to their accuracy. Thus the "worker safety rules" are unjustified.

We also believe it to he important to consider the type or severity of injury which may result from exposure to glyphosate formulations. Results of testing indicate that eye irritation which can result from contact with the concentrated material is on the order of that which would be experienced if shampoo were to contact the eyes. This irritation is very mild and quickly clears up. No reports of any permanent injury have ever been received. Reports of skin irritation are rarely reported, but when they are they are usually that of a mild rash which takes place when the material contacts skin which has been abraded or scratched. This irritation is a mild rash which quickly subsides. Again, no reports of any permanent injury have ever been received.

The Agency statement that CDFA data ranks glyphosate third in the number of illnesses reported for exposure to glyphosate fails to take into consideration the number of individuals who actually handled/used the product. To truly "rank" illnesses by pesticide one must look at the frequency of illness. Glyphosate is one of the most widely used pesticides in California. Data obtained from our regional operations office in California indicate that on a conservative basis, a minimum of 130,000 individuals handle and use glyphosate products for agriculture purposes in any given year. Utilizing the 144 exposures CDFA claims which may be due to glyphosate during the four year reporting period, a frequency of .028% or 28 exposures per 100,000 individuals handling, using the product can be estimated. Whereas we do not believe any level of injury is acceptable, this very low frequency in conjunction with the lack of severity of the reported exposures for glyphosate further supports our position that the registration standards additional "worker safety rules" are neither necessary nor required for glyphosate products.

Finally, we would add that labels for formulated glyphosate already warn the user to either avoid contact or do not allow contact with the material. Therefore, we could assume that those persons who reported irritations due to contact with these formulations failed to follow the

label directions. One could question if additional label language is necessary when the present language is clearly adequate and are not followed by some. Therefore, we believe that the glyphosate formulations are adequately labelled, the new worker safety rules are not justified and this requirement should be dropped.

Homeowner End-use Products
Page 14 - Paragraph 5

The Agency states that end-use products registered for homeowner use contain very low concentrations (0.1 - 10% active ingredient) and have very low acute toxicity (category III and IV). Therefore, the Agency will not require protective clothing for these products. Monsanto has recently registered with the Agency a Roundup L&G herbicide that a homeowner can use. The Roundup ODES acute toxicology categories are IV, IV, III, and IV respectively. This Roundup L&G herbicide contains 18% active ingredient; therefore, we request that the Agency also not require protective clothing for this 18% active ingredient formulation.

Page 15 - Paragraph 1

The Agency states that the acute dermal toxicity data place glyphosate and its formulated products into Toxicity Category III. This is not correct. Glyphosate and its formulated agricultural products all have dermal LD_{50} values which are greater than 5000 mg/kg, placing them into the Toxicity Category IV. Please correct this error.

ECOLOGICAL CHARACTERISTICS

Terrestrial Organisms
Page 15

The acute oral toxicity studies with bobwhite quail submitted to the Agency (WL-78-27; Accession No. 234395), show that the LD_{50} of glyphosate is greater than 4640 mg/kg, not 2000 mg/kg as stated. Therefore, glyphosate is considered to be practically non-toxic to bobwhite quail on an acute oral basis, not sligbtly toxic as stated.

Also, in the same paragraph, based upon submitted data (HL-73-75 and HL-73-76; Accession No. 94171) the eight day dietary LC_{50} values for both quail and mallard ducks are greater than 4640 mg/kg, not 4000 mg/kg as stated. Please correct this error.

Plant Protection
Page 16

The Agency is requiring that tier 1 testing be performed with glyphosate. Monsanto will respond within the Agency's allotted timeframe.

Endangered Species
Pages 16 and 17

The Agency has requested additional product labeling for crops, rangeland, pastureland and silvicultural sites. It is our understanding that this is an EPA policy, and we therefore have no objection to adding the endangered species information to our labels. However, since the bulletin is not available, we do not believe we can comply with these requirements. We trust that the Agency will concur that this language should not be added to the label until the referenced bulletin is available.

Residue Data, Page 19 - Paragraph d

The Agency states that available methods for analysis of residues of glyphosate and its major metabolite (AMPA) in or on plant comodities or water are adequate for data collection. We request that the words "and enforcement" be added to the end of this sentence.

Regulatory Position and Rationale
Page 21 - Item 4

The Agency states "available acute dermal toxicity data placed technical glyphosate" and its formulated products for agricultural use in toxicity category III. Tbis is not correct. Glyphosate and its formulated agriculture products all have dermal LD_{50}s which are greater than 5000 mg/kg, placing them into toxicity category IV. Please correct this error.

Page 21 - Item 5

The Agency is requiring that labeling and all end-use products, except those labeled for homeowner use only, bear "Worker Safety Rules" requiring protective clothing requirements (face shield or goggles), chemical resistant gloves, chemical resistant apron and chemical resistant shoes, shoe coverings or boots. Based upon the low degree of acute dermal toxicity (Category IV) and dermal irritation potential (Categories III and IV), the requirements for chemical resistant aprons and shoes, shoe coverings, or boots are not justified. All current glyphosate formulation labels comply with labeling requirements as specified in 40CFR Section 162.10; and these labels, therefore contain the appropriate precautionary statements required by FIFRA, such as DO NOT get in eyes, on skin or on clothing. As stated previously, we do not believe this additional label language is justified and therefore request it be deleted.

Crop Rotation Restriction
Page 22 - Item 7

The Agency is imposing a label restriction prohibiting the rotation of food or feed crops to glyphosate treated soil unless glyphosate is registered for use on those crops. The Agency presently has on a file a wide range of glyphosate studies which demonstrate that residue levels in crops grown following preplant glyphosate applications are non-detectable. In addition, uptake/metabolism studies are on file which likewise show low to non-detectable residue levels; thus providing additional proof that the plants do not take glyphosate up from the soil. Glyphosate, upon contact with soil, immediately becomes tightly bound to various soil components, particularly clay. Consequently, glyphosate is not readily taken up from the soil by the root system of plants. As a result, uptake of glyphosate and its major metabolite (AMPA) is less than 0.1% of the amount applied.

Glyphosate does not accumulate in the soil, and it dissipates rapidly in soils under a variety of environmental conditions. The half-life for dissipation of glyphosate in soil is 6 weeks or less, and the average time required for the dissipation of 90% of the observed initial glyphosate in soil is less than 4 months. Therefore, glyphosate, in addition to not being available for plant uptake, is also rapidly dissipated.

On August 6, 1986, Monsanto requested the Agency to approve a reduction in the preplant crop rotation restriction to 3 months. We urge the Agency to review the submitted request and approve it as soon as possible.

According to the rotational crop restrictions as stated in Federal Register Vol. 49, No. 188, September 26, 1984 page 37989, labeling must include a restriction limiting rotation (or replanting after crop loss) for a specified period of time after pesticide application not to exceed 18 months. This is in contrast to what the Agency states on page 22 where there is a label restriction prohibiting the rotation of food or feed crops in glyphosate treated soils unless glyphosate is registered for use on those crops. Therefore, we question the Agency's deviation from this rule. Regardless, we request the Agency to approve the requested 3 month crop rotation restriction. We would propose that no changes be made to the label until the crop rotation request is reviewed and approved.

Label Restrictions
Page 22 - Item 8

The Agency is imposing a label restriction prohibiting the use of glyphosate on rice fields in which crayfish and catfish are included in cultural practice. These additional label amendments should not be needed since a tolerance for fish has been established for glyphosate, and the crayfish restriction is presently on the Rodeo herbicide label. Tolerances are pending for shellfish. It is our understanding that the shellfish tolerances will be set in the near future; hence, this proposed label restriction should not apply.

Page 23 - Paragraph 2

The Agency is imposing label restrictions prohibiting the use of water containing glyphosate from rice cultivation for irrigation of feed or food crops not appearing on the glyphosate label. Glyphosate is applied to weeds growing in fields before the field is tilled or the rice crop planted. Glyphosate is tightly bound to the soil and water is not able to extract it so that it would be found in solution. In addition, glyphosate is rapidly biodegraded, has a short half-life and rapidly dissipates. Thus, preplant applications of glyphosate will not result in flood water containing glyphosate. Monsanto therefore believes this restriction is not necessary and request this requirement be removed.

Page 24 - Item 12

The Agency requires residue data together with a petition for establishing tolerances, if necessary, for sugarcane forage and pineapple forage. Alternatively, a statement may be placed on the label restricting the grazing or feeding of treated commodities. Monsanto will request the EPA to approve the feeding and grazing restriction for pineapple and sugarcane forage.

Page 24 - Item 13

The Agency intends to disapprove the registrations of various 24(c) sorghum labels for the use of selective equipment. Alternatively, residue data and petition for tolerances must be submitted proposing tolerances on sorghum forage, fodder and hay reflecting these uses. Since the Agency approved glyphosate tolerances (on 5/28/86) for the use of selective equipment on sorghum, and has approved this use on the Roundup label. This issue should now be resolved. Therefore, Monsanto will cancel these specific 24 (c) labels on sorghum/selective equipment.

Tolerance Listings
Pages 25 and 26 - Items 14, 15, & 16

The Agency has required various changes be made in the tolerance listings.

Monsanto agrees to modify the tolerance listings that are stated in Items 14, 15 and 16. Our specific compliance comments are included in the attached Part G.

The Agency is requiring additional data on crops treated with irrigation water containing residues of glyphosate. Monsanto has submitted data (conducted by V. F. Burns, U.S.D.A. at Prosser, Washington; EPA Accession Number 94684)) that contains valid data to answer irrigation water questions. In the Washington study, the following crops alfalfa, field beans, sorghum, squash, sugarbeets and tomatoes were treated with sprinkler irrigation water for 3 days containing either 0.02, 0.22 and 2.21 ppm glyphosate. These crops were then harvested and analyzed for residues of glyphosate. Except for sorghum, all commodities sprinkler irrigated with water containing glyphosate residues at the 2.21 ppm level contained no detectable residue at harvest. At harvest, residue levels as high as 0.18 ppm glyphosate were detected in sorghum stover after treatment with irrigation water containing 2.21 ppm glyphosate (see Table 13 of the report for further details).

We believe this study represents a worst case scenario since the crops were treated for 3 days with irrigation water containing set levels of glyphosate. This will not be expected to occur in nature since glyphosate levels in water will rarely be detected and when detected will occur at levels below these used in this study. In addition, the glyphosate, if present, will not be present for long periods of time. If water is taken from irrigation canals it should then only be present for a period of hours to a few days; and if lake or pond water is used, it could then be present for a period of a few weeks; but it will be at low levels which will continue to decline.

Therefore, we conclude that should residues not be detected in these crops after treatment under this worst case scenario, then there would be no reason to believe they could be present under actual conditions; and therefore, these additional residue requirements should be withdrawn.

Page 26 - Item 18

The Agency states "Registrants must provide or agree to develop additional data, as specified in the Data Appendicies, in order to maintain existing registrations.

Since Monsanto does not have any registered glyphosate manufacturing-use (MP) products, comments concerning compliance with table B (pages 94 through 97) are not necessary.

Monsanto comments for generic data requirements for glyphosate (pages 50 through 92) are outlined in the attached Part G.

Required Labeling
Page 27

The Agency states that all labeling changes must appear on all products in channels of trade by June 30, 1988. Since we do not know when we will reach agreement with the Agency on what changes are required and it would be essentially impossible to relabel all products in the channels of trade by June 30, 1988, Monsanto requests this statement be changed to read as follows:

> After 12 months from the date of agreement with the Agency on labeling changes, all labeling changes must appear on all glyphosate products released for shipment.

Required Labeling
Page 27 - Item D

Since Monsanto does not have any manufacturing use products (MP), a response is not needed concerning manufacturing use products labeling. Therefore, all labeling submitted with this registration standard will only involve end-use products.

Pages 27 to 34 - Items 1 to 5

Depending on the agreement reached with the Agency concerning labeling requirements, the specific statements may be modified or deleted from those listed on pages 27 to 34. Therefore, it is impossible to agree to acceptable label terminology until the Agency has reviewed our comments and Monsanto reaches agreement with the Agency.

WHY THE GLYPHOSATE MOUSE ONCOGENCITY STUDY
IS NOT REQUIRED

The Agency requests a repeat of the chronic feeding/oncogenicity study in mice to fully address the questions of "... whether the apparent effects noted in the mouse study [renal tubular adenomas] are biologically relevant." The results of the mouse bioassay do not provide positive, or even suggestive, evidence of carcinogenicity. The most that can be said is that the results were equivocal as, in fact, the Scientific Advisory Panel stated. Furthermore, the SAP pointed out the fact that this equivocal finding occurred only at a dose level that exceeded the MTD. Quoting from the SAP report, "... no oncogenic effect is demonstrated using concurrent controls" and"... the level of concern raised by historical control data was not great enough to displace putting primary emphasis on the concurrent controls." There appears to be no justification for requiring the repeat of a study with equivocal findings at a single site, only at dosage levels exceeding the MTD.

Several expert toxicologists intimately familiar with the glyphosate chronic/oncogenic mouse study results, and personally involved in the SAP hearing on this issue, were asked to evaluate the need for a repeat study. All experts agreed that additional testing is not justified since the current study was conducted at levels exceeding the MTD and failed to demonstrate a treatment-related oncogenic effect. Their evaluations are enclosed in this part.

As discussed previously, the fact that Monsanto has agreed to repeat the chronic/oncogenic rat study with glyphosate diminishes even further the justification for a repeat mouse study. As pointed out by Dr. Farber at the SAP hearing, "If in fact there wasn't a remaining MTD issue in regard to the rat study, and the rat was run at a somewhat higher level and nothing was seen, then basically the whole thing comes out as no evidence of carcinogenicity." The results of the current rat and mouse studies, along with results to be obtained from a repeat rat study, should be sufficient to assess the oncogenic potential of glyphosate. A repeat mouse study is not necessary.

Finally, based upon a review of the principles expressed in the Agency's draft "Position Paper on Maximum Tolerated Dose (MTD) in Oncogenicity Studies", it is clear that the chronic/oncogenic mouse study was conducted at dosage levels which greatly exceeded the upper limit of 7,000 ppm required for mouse studies. Furthermore, none of the requirements listed in that document which would necessitate a study are fulfilled for the mouse study (see Attachment 1).

Statement of Robert A. Squire
Concerning a Possible Repeat of
The Glyphosate Bioassay in Mice

Repeat of a chronic animal bioassay can be justified on the basis of several deficiencies but none of them are present in the case of glyphosate. The maximum tolerated dose was met or exceeded in a well validated study, and there was no biologically or statistically significant increase in tumors.

All pathologists who examined the mouse kidney slides and data expressed the view that the renal adenomas in male mice could not be attributed to the test compound. It is difficult to see a basis on which a study can be considered positive or even suggestive if there is no statistically significant increase in tumors and the scientists directly involved find no biological evidence of a compound-related tumorigenic effect. As I indicated in my letter of September 29, 1986, the weight of evidence including the absence of preneoplastic lesions in addition to the 3 adenomas in high-dose males strongly suggest that the tumors were naturally occurring. This view was shared by Dr. Marvin Kuschner and the original pathologists.

Attachment A from The Environmental Protection Agency document entitled "Guidance for the Regulation of Pesticide Products Containing Glyphosate" states on page 6 that "Glyphosate produced

an equivocal oncogenic response in the mouse, causing a slight increase in the incidence of renal tubular adenomas .... ". There is clearly a presumption by EPA that the tumors were compound-related. By definition, such a presumption cannot be supported by equivocal data, and it was not supported by the Scientific Advisory Panel findings. As stated in their Report, ".... no oncogenic effect is demonstrated using concurrent controls", and ".... the level of concern raised by historical control data was not great enough to displace putting primary emphasis on the concurrent controls".

The most severe judgement applied to the study by the SAP was also that the finding was "equivocal". Equivocal data are frequent in chronic bioassays in the National Toxicology Program and elsewhere. Unless such a finding occurs in a study that failed to administer an MTD, it does not provide a basis for retesting. Where only equivocal findings result, even after long-term exposure to maximum tolerated doses, it is difficult to believe that a carcinogenic effect may have been "missed". Or if such an effect was missed, that it could be demonstrated by retesting within any reasonable experimental design limits. If our years of animal testing experience have taught us anything, it is that such tests are relatively imperfect assays and that retesting rarely resolves initial disputes. Furthermore, to require retesting in cases of equivocal findings would, I fear, set a precedent that would overwhelm toxicology resources and produce endless delays in chemical testing.

In summary, the weight of evidence indicates that no tumorigenic effect was evident in mice chronically exposed to glyphosate at a maximum tolerated dose. There is no reason to believe that retesting would produce a different result.

Robert A. Ippen

October 8, 1986

OCT 16 1986

PATHCO INC.
P.O. Box 2489 Gaithersburg, MD 20879 (301) 831-8518

October 14, 1986

Dr. Timothy J. Long
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St. Louis, Missouri 63167

Dear Tim:

You asked me to comment on EPA's request that Monsanto repeat the mouse oncogenicity study for Glyphosate because of what EPA terms the equivocal finding of renal tumors in the kidneys of male mice. As you know, I do not believe these neoplasms are related to administration of Glyphosate and so feel the current test is adequate.

However, assuming there is some question regarding the significance of these lesions, I feel a retest under the same conditions would not add any new information. Two ways to increase the sensitivity of a carcinogenicity test are 1) to increase the number of animals and/or 2) to increase the dose. The EPA has suggested that the number of animals/group be increased in order to increase the statistical power of the study. It seems to me that in order to prove conclusively statistically that these neoplasms are or are not related to Glyphosate would require a "megamouse" study. The cost for such a study would be extremely expensive. With regard to increasing the dose in a new study, based on the data from the subchronic and chronic mouse studies, I think a higher dose would likely compromise the study. In fact, there is concern that the dose already tested (30,000 ppm or 3% of the diet) was too high. The EPA has proposed, in a "Position Paper on Maximum Tolerated Dose (MTD) in Oncogenicity Studies", that the maximum dose in a mouse oncogenicity study should be 7,000 ppm (0.7% of the diet). Thus, the highest dose in the Glyphosate chronic mouse study far exceeds EPA recommendations. If the EPA recommendations for the high dose, i.e. 7,000 ppm, had been followed, it is possible that even at 30,000 ppm the mild toxic changes observed would not have been observed. Indeed, at 5000 ppm no toxic effects were observed.

In the same position paper, EPA presents a decision tier scheme for determining whether a chronic study needs to be repeated. Based on this scheme, there does not appear to be

any reason to repeat the mouse oncogenicity study for Glyphosate. The only possible areas of concern would be those related to an oncogenicity study in a second species. I understand that Monsanto is intending to repeat the rat oncogenicity study and, therefore, it would seem that these areas will be addressed.

Based on EPA's guidelines, it appears that they have adequate information from the current mouse oncogenicity study to adequately assess potential human risk and that a repeat of this study would be for academic curiosity.

Sincerely,

Dawn G. Goodman, V.M.D.
Diplomate, ACVP

DGG/ma

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5 1 1986

October, 25, 1986

Timothy J. Long, Ph.D.
Monsanto Company
800 N. Lindbergh Boulevard
St. Louis, Missouri 63167

Subject: Roundup(R)
Chronic Mouse Study

Dear Dr. Long,

I have reviewed the arguments for and against repeating the mouse study. I agree with your conclusion that it has no merit to initiate an additional experiment. The reasons are the following.

1. As I pointed out in my evaluation of 10-17-85, the CD-1 mouse has a high background incidence of neoplasms in different organs. The historical data on kidney tumors in this strain showed a relative large variation in their spontaneous incidence. I am certain that a repeat study would not lead to more meaningful data.

2. Because of the high incidence of spontaneous neoplasms in this mouse, one should give strong consideration to the following:

a. There are large numbers of initiated cells in many of the organs (expression of true carcinogenicity of whatever initiated these cells).

b. The toxic effect of any chemical could cause activation of these initiated cells and also promote tumor growth. This could occur in the primary target organ of the toxicant or in secondary organs. Roundup did not show any

renal toxicity, therefore, no activation or promotion could have taken place. No significant tumor development was present related to the dose of the material, and by comparison to historical data.

3. The genotoxic tests of the material were negative. This supports strongly the argument that Roundup is not an initiator (carcinogen).

In my opinion the above arguments strongly deny a repeat study with the CD-1 mouse. To satisfy the requirements of the agency a rat study is indicated.

Sincerely yours,

K. Stemmer

Klaus L. Stemmer, M.D.

ATTACHMENT 1

Glyphosate Mouse Oncogenicity Study (BD-77-420)

Monsanto believes that it is not necessary to repeat the glyphosate mouse oncogenicity study (BD-77-420). If one applies the decision tier scheme for determining the need to repeat oncogenicity studies as discussed in the EPA position paper on maximum tolerated dose (MTD)[1], it is apparent that none of the criteria necessitating a repeat study have been met. Outlined below is a level by level discussion of each of these criteria and the reasons why none have been met for the study in question.

Level 1 - Nearness to the Apparent MTD

"If the highest dose tested (HDT) is greater than or equal to one-half the apparent MTD, as judged from subchronic data or other chronic studies, no retesting is required."

Monsanto Response: The HDT in the glyphosate mouse oncogenicity study (30,000 ppm in the diet) was selected based upon the results of a 90-day subchronic mouse feeding study conducted at dietary concentrations of 5,000, 10,000, and 50,000 ppm. Evidence of subchronic toxicity, as evidenced by reduced body weight gain, was observed at 50,000 ppm. Body weight gains were reduced 24% and 18% for males and females, respectively. No effect upon body weight gain was observed at 5,000 or 10,000 ppm. It was felt that 50,000 ppm would be too high for a lifetime study. Body weight effects due to prolonged exposure at such a high level would probably be life threatening. Therefore, the HDT was chosen at 30,000 ppm. Since this concentration is greater than one-half the apparent MTD in the 90-day study (50,000 ppm), the first criteria necessitating a repeat study has not been met.

Furthermore, the HDT exceeds by greater than four-fold the dosage of 1 gram/kg/day (7,000 ppm for mice) which the Agency states[1] as an adequate upper limit for assessing human risks from animal oncogenicity studies with pesticides.

Level 2 - Demonstrated Oncogenicity

"If the test substance is demonstrated to be an oncogen in another species, retesting is required."

Monsanto Response: Glyphosate was not oncogenic in a 26-month rat feeding study (BD-77-416). This study had previously been accepted by the Agency as a valid study demonstrating lack of oncogenic potential. However, the Agency has expressed the concern that a MTD may not have been demonstrated in this study. Monsanto has agreed to repeat the rat oncogenicity study. Therefore, unless the repeat rat study were to demonstrate oncogenic potential, there is currently no justification for a repeat mouse study based upon the criteria at Level 2.

Level 3 - Genotoxicity
"If no genotoxicity is demonstrated in an acceptable battery of tests including one study each to detect effects at the gene, chromosome, and DNA level, consideration at the next level is required."

Monsanto Response: The results of an extensive battery of genotoxicity assays designed to assess each of these endpoints have uniformly been negative. Therefore, the criteria for retesting at this level have not been met, and consideration at level 4 is required.

Level 4 - Oncogenicity of Structural Analogs
"If structural analogs of the test substance or known metabolites have been shown to be oncogenic in animals or man, retesting is required."

Monsanto Response: Neither glyphosate nor any of its known metabolites are structurally related to any known oncogen. Thus, the criteria for retesting at this level have not been met.

Level 5 - Absolute Value of HDT
"If the HDT is 0.5 gm/kg b.w./day, no retesting is required."

Monsanto Response: The HDT in the lifetime mouse study was much greater than 0.5 gm/kg/day. For male mice, the time-weighted average daily exposure at the HDT was 4.84 gm/kg/day. The corresponding figure for female mice at the HDT was 5.87 gm/kg/day. According to this criteria, therefore, retesting is not required.

Level 6 - HDT Relative to Dose Tested in Second Species of an Oncogenicity Study with an MTD
"If the HDT in the study under evaluation expressed in mg/kg/day, is at least equal to the HDT in mg/kg/day in an acceptable oncogenicity study in another species, then no retesting is required. If, however, the HDT is less than ..., consideration at the next level (level 7) is required."

Monsanto Response: As discussed in Level 2, another oncogenicity study has been conducted with glyphosate in rats (BD-77-416). In that study, the HDT was 31 and 34 mg/kg/day for male and female rats, respectively. The HDT in the mouse study was 150-170 times greater than that in the rat study. Furthermore, the maximum dosage level that would be tested in the planned repeat rat study is 20,000 ppm. The HDT in the mouse study exceeds this dosage level (1000 mg/kg) by greater than four-fold. Therefore, consideration at level 7 is required.

Level 7 - Margin of Safety (MOS) Calculated for HDT vs Human Exposure
"If the MOS (ratio) between the HDT and the highest expected level of human exposure is greater than or equal to 1000, no retesting is required."

Monsanto Response: If one uses the Theoretical Maximum Residue Contribution (TMRC) based upon existing tolerances (1.4238 mg/day) as an upper bound on expected human exposure, then there is at least a 200,000 fold MOS* between the HDT in the mouse study and expected human exposure. Therefore, according to the criteria at this level, no retesting is required.

*HDT = 4840-5870 mg/kg/day
TMRC = 1.4238 mg/day
Thus: (4840 mg/kg/day)(60 kg man) ÷ 1.4238 mg/day = 203,961

References

[1]Harris, J.E., Farber, T.M., Engler, R., Quest, J.A., and Skinner, C.S.; Position Paper on Maximum Tolerated Dose (MTD) In Oncogenicity Studies - DRAFT. April, 1986.

REPLY TO COMMENTS ON THE ENVIRONMENTAL FATE OF GLYPHOSATE IN THE GLYPHOSATE REGISTRATION STANDARD

In the document "Guidance for the Reregistration of Pesticide Products Containing Glyphosate as the Active Ingredient", Case Number 0178, June 30, 1986, statements were made in section III Agency Assessment: Environmental Characteristics (pages 13 - 14), section IV Regulatory Position and Rationale (page 22), and in Table A (pages 77 - 78) concerning the glyphosate environmental fate data base. Specifically, there were judged to be no data or insufficient data available regarding photodegradation, laboratory soil and aquatic metabolism, mobility, and confined rotational crops.

Examination of the Registration Standard Bibliography, which contains "Citations Considered to be Part of the Data Base Supporting Registrations under the Glyphosate Standard" showed that there are a substantial number of study reports which have been submitted to the Agency for the purpose of supporting glyphosate registration and assigned an accession number, but which are not included in the bibliography. In addition, examination of the reviewer's comments pertaining to these Environmental Fate subjects revealed that additional studies which were most pertinent to these subjects were not considered in assessing fulfillment of the proper requirement even though they were included in the Registration Standard Bibliography. Finally, very few of the large number of public literature references which contain data pertinent to these issues were considered in reaching the stated conclusions.

Monsanto maintains that there are sufficient data readily available from these sources to satisfy the majority of the requirements which were judged to be inadequately met in the Registration Standard. The evidence from all of these studies clearly demonstrate that glyphosate presents no potential of harm to the environment because it is rapidly and irreversibly bound to soil or sediment, making it largely unavailable to other living systems, and that microbial metabolism or photodegradation convert it to only one significant transient metabolite prior to complete mineralization.

In the following discussion, detailed consideration of the data which were reviewed and those which were not retrieved in each of the pertinent subject areas is presented. A bibliography of pertinent public literature references is also attached.

Photodegradation. The Registration Standard states that photodegradation studies in air, water, and soil are required, and that no data have been submitted. Since glyphosate is an extremely nonvolatile amino acid derivative which exists as a salt under environmental conditions, photodegradation studies in air are

essentially impossible to conduct and not justified by inhalation exposure. Two Monsanto reports directly address photodegradation in water and on soil: Monsanto Report No. FR 258 (Accession No. 228130) by Rueppel and Brightwell, 1972; and Monsanto Report No. MSL-0598 by Brightwell, 1978 (This report will be submitted to the Agency in the near future.). FR 258 was not considered by the reviewer nor is it listed in the Registration Standard Bibliography. Although both studies may contain minor procedural differences from those currently recommended because they were conducted during the 1970's, they both are valid and appropriate studies. These minor differences involve the frequency of sample collection or the duration of exposure in real sunlight-days. In addition, there have also been independent photodegradation studies reported in the public literature. Overall, results from these experiments demonstrated that photodegradation is slow and highly dependent upon the presence of metal ions. When photodegradation occurred, aminomethylphosphonic acid was produced, which is also the major residue produced by microbial breakdown of glyphosate under environmental conditions.

Aerobic Soil Metabolism. Only one study was reviewed with regard to this requirement and was judged to be scientifically invalid and inadequate: MRID 00108140 by Hilton et al., 1975. Since this study was only conducted to obtain supplemental information on glyphosate's behavior in Hawaiian soils, this conclusion is probably justified based on the study reviewed. Monsanto has submitted two studies to address this subject: Monsanto Report No. FR 269 (Accession No. 228130, MRID 00108181) by Rueppel and Brightwell, 1972; and Monsanto Report No. FR 271 (Accession No. 228130, MRID 00108182) by Rueppel et al., 1972. Both of these reports were considered by the reviewer under different subjects and they were cited in the reviewer's references but they are not included in the Registration Standard Bibliography. In FR 269, the aerobic metabolism studies were conducted in a fashion more similar to aquatic metabolism studies, but used distilled water. For this reason, the results are also primarily of supplemental value, although the nature of the metabolites produced and bound to soil was investigated and is clearly pertinent. In FR 271, the experiments were conducted in a fashion which should satisfy the requirements. The reviewer's comments concerning the need to "accurately assess the decline" of glyphosate in the soil are confusing since these metabolism studies are principally designed to define the nature of the degradates; many additional studies using unlabeled glyphosate have already been conducted to accurately define the rate of dissipation.

Anaerobic Soil Metabolism. One study (MRID 00108140 by Hilton et al., 1975) was considered by the reviewer and judged to be inadequate and invalid for a variety of reasons. Monsanto doesn't dispute those conclusions for that study as discussed in the previous section. In fact, no study has been submitted which adequately addressed the subject of anaerobic soil metabolism; however, since data concerning anaerobic aquatic metabolism are

available, anaerobic soil metabolism studies should not be required since the guidelines state that anaerobic aquatic metabolism can substitute for anaerobic soil metabolism.

Aerobic Aquatic Metabolism. Two studies were reviewed on this subject: Monsanto Report No. MSL-0207 (Accession No. 234108, MRID 00108192) by Brightwell and Malik, 1978; and Monsanto Report No. FR 269 (Accession No. 228130, MRID 00108181) by Rueppel et al., 1972. Although both were available to the reviewer, only the first is included in the Registration Standard Bibliography. The reviewer's comments that the waters used in MSL-0207 were not mixed with sediment or soil are true, although another study (Monsanto Report No. FR 276 (Accession No. 228130) by Henshall and Brightwell, 1972) does include experiments of this nature. The term "complete water characteristics" is not sufficiently definitive to allow unambiguous compliance, although both the pH and the source of the waters used were provided. The reviewer cited a lack of complete data on the characterization of radioactivity in some samples. This deficiency appears to involve a few entries in the data tables at early timepoints which do not effect the conclusions of the study and is viewed as an inconsequential deficiency by Monsanto. Additional data on the dissipation of unlabeled glyphosate in environmental waters (Monsanto Report No. FR 372 (Accession No. 94684, MRID 00039381) by Kramer et al., 1975; and Monsanto Report No. FR 325 (Accession Nos. 94162 and 94163, MRID 00038908) by Beasley et al., 1974) are also available. Objections cited by the reviewer to the experiments in FR 269 are valid to some extent because the study was conceived as a soil metabolism study rather than an aquatic study at a time prior to finalization of standardized procedures. The specific comment that the results from FR 269 are "too variable to assess the decline" is not justified because many studies with glyphosate demonstrate that the physical state and rate of degradation of glyphosate in natural systems are highly dependent upon the components in the system; thus the variability observed is an experimental fact not a deficiency in the procedure.

Anaerobic Aquatic Metabolism. In this section also, only one of several available studies was apparently reviewed. The study reviewed was FR 269, which was just discussed above in the section on aerobic aquatic metabolism; the same evaluation of the reviewer's comments applies. A more appropriate study for review would have been Monsanto Report No. MSL-0207 (Accession No. 234108, MRID 00108192) by Brightwell and Malik, 1978, which had just been reviewed and judged to be scientifically valid under the subject of aerobic aquatic metabolism. In MSL-0207, anaerobic aquatic metabolism studies were conducted with combined water and sediment in a fashion that was otherwise very similar to the aerobic experiments; thus, the only possible objections the reviewer might have made should therefore involve the issues of "complete water characterization" or the lack of complete radioactivity characterization at the earliest timepoint. Additional anaerobic aquatic studies are described in Monsanto Report No. MSL-0598 (available for submission to the Agency) by Brightwell, 1978.

Leaching and Adsorption/Desorption. In this category, six studies are mentioned by the reviewer as having been reviewed although only five are cited. Among these, MSL-0207, referred to in the prior two sections, is judged to fulfill the entire requirement with the small exception that the Cattail Swamp sediment was not completely characterized. In fact, two sediments were used in the studies described in the report, and only one of the two was completely characterized along with the eight soils which were also used and characterized. Unfortunately, the adsorption/desorption experiments were conducted with the partially-characterized sediment, and Monsanto admits that this is a minor deficiency in this study. This deficiency clearly doesn't alter the overall conclusion that glyphosate is very tightly bound to soils, which is accepted in numerous statements throughout the Registration Standard document (for example, pages 5, 14, and 21). Additional data on this topic not considered by the reviewer are included in Monsanto Report No. FR 258 (Accession No. 228130, not included in Registration Standard Bibliography) by Rueppel and Brightwell, 1972; and Monsanto Report No. FR 275 (Accession No. 228130, MRID 00039943) by Henshall and Brightwell, 1972, as well as in the public literature. Monsanto Report No. MSL-5393 (available for submission to the Agency) by Livingston et al., 1986, contains adsorption/desorption data for N-(phosphonomethyl)iminodiacetic acid, a closely related compound.

Rotational Crops. One study is mentioned by the reviewer as having been reviewed although two are then cited: Monsanto Report No. FR 271 (Accession No. 228130, MRID 0108182) by Rueppel et al., 1972; and Monsanto Report No. FR 274 (Accession No. 228130, MRID 0180183) by Henshall and Brightwell, 1972. Neither of these studies are included in the Registration Standard Bibliography, and neither was conducted for the purpose of studying rotation crops. Instead, each was designed to study the behavior of glyphosate in soils in which plants had been included to more closely simulate field conditions. The two appropriate studies, only one of which is included in the Registration Standard Bibliography, were apparently not reviewed: Monsanto Report No. FR 406 (Accession No. 96398, MRID GS0178-003) by Suba, 1976; and Monsanto Report No. MSL-0882 (Accession No. 241426) by Brightwell and Cooper, 1979. An additional study (Monsanto Report No. FR 470 (Accession No. 96398, MRID 00108159) by Beasley, 1977, conducted with unlabeled glyphosate, is also available. When these studies are properly considered, Monsanto believes that the rotation crop issue will be resolved.

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Response to the EPA With Regard to the Statements Published in the Glyphosate Registration Standard Concerning the Laboratory Studies on Pesticide Accumulation in Fish.

In the document "Guidance for the Reregistration of Pesticide Products Containing Glyphosate as the Active Ingredient," Case Number 0178, statements were made by the Agency that based upon the five studies reviewed, two of which were determined to be scientifically valid, the data requirements were not fulfilled. Monsanto disagrees with these conclusions, primarily since the studies which were submitted to meet these requirements were either not reviewed or overlooked by the Agency during the review.

Examination of the Bibliography of the Registration Standard showed that not all of the study reports pertinent to the accumulation of glyphosate in fish were considered in the reviewer's evaluation. These reports were submitted to the Agency in support of the glyphosate registration and were assigned EPA accession numbers. Included in these studies are the following reports: Monsanto Final Report No. 372 (EPA Accession No. 94684 and 95356) by Kramer, 1975; Monsanto Report No. MSL-0569 (EPA Accession No. 97762) by Kramer and Beasley, 1978; Monsanto Report No. MSL-1116 (EPA Accession No. 99411) by Purdum, 1980. Although all of these reports were available within the Agency, it appears as if they were not considered.

With regards to the reports which were reviewed by the Agency, Monsanto must take serious issue with the reviewer's comments concerning validity of the data. First, these studies were conducted as static studies based upon the Agency's request as part of the requirements for fulfilling an aquatic use petition for pesticide applications to ponds/lakes, rice paddies, freshwater levees, and tidewater areas. Additionally, the reviewer's comments concerning variability of the data in some tissues, characterization of residues, and the aging of the test substance would not be appropriate when the total data package that the agency has is considered. The variability of data in crayfish tissue, suggested by the reviewer to invalidate the study, is not considered unusual by aquatic toxicologists experienced in using crayfish as a test species under static conditions. These reports comprising the total data package include Monsanto Report No. MSL-2056 (EPA Accession No. 246876) by Grabiak, 1982; Monsanto Report No. MSL-2937 (EPA Accession No. 71696) by Purdum and Grabiak, 1983; Monsanto Report No. MSL-2952 (EPA Accession No. 71695) by Purdum and Grabiak, 1983; Monsanto Report No. MSL-5018 (EPA Accession No. 260497) by Chott, Livingston and Schafer, 1985; Monsanto Report No. MSL-5019 (EPA Accession No. 260534) by Chott and Livingston, 1985; Monsanto Report No. MSL-5045 (EPA Accession No. 260497) by

Purdum, 1985; Monsanto Report No. MSL-5059 (EPA Accession No. 260534) by Purdum, 1985. All of these above referenced studies have been reviewed by the Residue Chemistry Branch of the Agency and all issues associated with the Aquatic Use Petition #3F2956 for glyphosate have been resolved to the satisfaction of the Residue Chemistry Branch and Monsanto in a memorandum dated April 10, 1986 received from the Agency.

REPLY TO "WORKER SAFETY RULES" LABELING REQUIREMENT

Page 14, 2nd paragraph

All current glyphosate formulation labels comply with labeling requirements as specified in 40 CFR Section 162.10; and these labels, therefore contain the appropriate precautionary statements required by FIFRA, such as Do Not Get in Eyes, on Skin or Clothing.

Available worker exposure and reported illness data do not support the Agency's proposal to require "Worker Safety Rules" requiring protective clotheing to appear on all labels for glyphosate formulated products intended for agricultural and aquatic uses.

The Agency references the California Department of Food and Agriculture (CDFA) reports which rank glyphosate third in the number of illnesses reported from exposure to pesticides. Monsanto has obtained the published CDFA reports for the four year period 1982-85. In addition, we requested from CDFA and were provided, the individual listing of each reported glyphosate exposure for this four year period. For each reported exposure, CDFA investigates the relationship between the reported exposure and the subsequent illness and determines the likelihood that the reported exposure actually caused the reported illness. The likelihood categories are (1) definite (2) probable - circumstantially likely but not definite, (3) possible - circumstantially uncertain but some likelihood exists (4) unlikely - very little likelihood of a relationship. In addition, CDFA categorizes each illness by job category. Categories include mixer/loader, hand or ground application, etc. Finally, each illness is classified as either eye, skin, eye/skin, or systemic.

The individual listing of each glyphosate illness reported allowed us to review the type of each exposure reported, the job category involved and the likelihood that the reported exposure actually caused the reported illness. This review indicated that a total of 245 exposures were reported during the four year reporting period. However, only 144 (58.8%) of these exposures were judged by CDFA to have a definite or probable likelihood of actually causing the reported illness. 98 (68.1%) of these 144 exposures involved exposure to the eyes; 38 (26.4%) were exposures to the skin. Eye exposures were primarily to individuals mixing, loading and applying the product. In the four year period, only six incidents of skin exposure to mixers or loaders were reported. Of greatest significance, little or no data is provided indicating the severity of reported illnesses. No reports of hospitalization are contained in the listings for glyphosate exposures.

This lack of qualification regarding severity of effects reported in the CDFA data supports Monsanto's firm position that the use of the term "illness" in describing glyphosate incidents in California is a misnomer. These incidents should be referred to simply as "exposures". An exposure to glyphosate does not automatically denote "illness".

The CDFA data confirm the agency position that exposures reported for glyphosate formulations are primarily eye and skin irritation. The data also confirm the agency position that eye irritation is primarily occurring to mixers, loaders and applicators. It does not support a contention that the nature of these exposures is such to require stringent safety precautions. The data, also, do not confirm the agency position that skin irritation is occurring to mixers and loaders. Only six incidents in four years report dermal irritation for this job activity.

The Agency statement that CDFA data ranks glyphosate third in the number of "illnesses" reported for exposure to glyphosate fails to take into consideration the number of individuals who actually handled/used the product. To truly "rank" exposures by pesticide, one must look at the "frequency of exposure". Glyphosate is one of the most widely used pesticides in California. Data obtained from our regional operations office in California indicate that on a conservative basis, a minimum of 130,000 individuals handle and use glyphosate products for agricultural purposes in any given year. Utilizing the 144 exposures CDFA claims were definitely or probably due to glyphosate during the four year reporting period, a frequency of .028% or 28 exposures per 100,000 individuals handling/using the product can be estimated. This frequency value, in conjunction with the lack of severity of the reported exposures for glyphosate further supports our position that "Worker Safety Rules" are neither necessary nor required for glyphosate products.

In addition to the CDFA data, there is one other source of "illness" reports concerning glyphosate exposure. From 1966 - 1980, the Agency maintained the Pesticide Incident Monitoring System (PIMS). Based on our previous review of the data in this system, a total of 40,677 pesticide incidents were reported to EPA. Only 109 (0.27%) of these incidents involved glyphosate. Further review of the glyphosate incidents indicate that only 35 of these incidents resulted in actual observed illness symptoms in the exposed individuals. Finally, we are not aware if any of these incidents reported were validated as to their accuracy. None of these exposures resulted in life-threatening situations or even hospitalization. In fact, the majority of the exposures resulted in minor symptoms for which the individual was treated locally and released. This extremely low incident rate and the lack of any reported severe or complicating symptoms again support our position that "Worker Safety Rules" can not be justified for glyphosate based products.

Page 21, No. 5

The skin and eye irritation properties of technical glyphosate formulation products do not warrant the imposition of "Worker Safety Rules" as decribed in the guidance document. The Agency states in the guidance document that technical glyphosate is not a primary skin irritant and is only minimally irritating to the eye. Quantitative results from EPA approved animal eye irritation studies of the glyphosate formulation for agricultural use demonstrate that according to the previous classification scheme for eye irritation, this formulation is no more irritating to eyes than common shampoos and detergents. The Agency states that the agricultural use product causes "some" dermal irritation. Animal skin patch studies do not support this statement. "Worker Safety Rules" simply can not be supported based on the results of standard animal skin and eye irritation studies.

One further issue regarding the skin and eye irritation properties of glyphosate formulations needs to be addressed. In the rationale for requiring "Worker Safety Rules" on all new glyphosate product labels for agricultural or aquatic use, the Agency highlights the differences in eye and skin irritation properties between technical glyphosate and formulations for glyphosate for agricultural use. The Agency should note that the glyphosate formulation for aquatic use does not demonstrate this difference in either skin or eye irritation properties when compared to technical glyphosate. Thus, while Monsanto believes that "Worker Safety Rules" as specified by EPA are inappropriate for all formulations of glyphosate, such requirements are even more inappropriate for the Rodeo aquatic use formulation.

Therefore, Agency justification for "Worker Safety Rules" is not supported by the factual data. Eye and skin irritation properties for both technical glyphosate and the agricultural formulation, based on valid animal studies do not support a "Worker Safety Rules" requirement. Review of both CDFA and PIMS exposure/illness data also do not support a "Worker Safety Rules" requirement.

In conclusion, we firmly believe that existing label language and recommendations regarding worker protection are sufficient and satisfactory and that the "Worker Safety Rules" requirement is unnecessary.

REPLY TO TABLE A

GENERIC DATA REQUIREMENTS FOR GLYPHOSATE

158.120 PRODUCT CHEMISTRY

DATA REQUIREMENT	COMMENT/STATUS
• Product Identity • Analysis and Certification of Impurities	Product Chemistry requirements (as outlined on page 50) for glyphosate TGAI were submitted to the Agency on 6/30/86.
• Physical and Chemical Characteristics	With the exception of 63-17 storage stability, the above submitted product chemistry information also contains TGAI information requested on page 51. EPA states "Storage Stability" is listed under "Product Chemistry" section 63-17. However, the 63-17 requirement should be a storage stability section under Residue Chemistry. Sample submission of TAGI and PAI for 64-1 will be submitted whenever the Agency asks for their shipment. Several of the reference numbers listed cannot be found in the Section IV. Bibliography Appendices. The missing references are listed below: MRID 00053002 MRID 00061553 MRID 00108102

158.125 RESIDUE CHEMISTRY

Monsanto will be collecting residue data on various crops during the 18 to 24 month allotted timeframes. In the meantime, we request that the current 40 CFR 180.364 not be changed until this additional residue information can be submitted to the Agency and the Agency has reviewed it.

DATA REQUIREMENT	COMMENT/STATUS
171-2-Chemical Identity	The required TGAI information was submitted to the Agency on 6/30/86 as part of a glyphosate product chemistry report. Therefore no further Monsanto action is required.
171-4-Nature of Residue (Metabolism) - Livestock	Monsanto agrees to conduct these studies on goats and chickens.

DATA REQUIREMENT	COMMENT/STATUS
171-4 Residue Analytical Method - Animals	Monsanto will provide the requested method.
Storage Stability	The storage stability requirement listed under Product Chemistry (see page 51, 63-17) should be listed under residue chemistry. Monsanto needs clarification from the Agency as to what is needed, and when these data should be submitted.
171-4-Magnitude of Residue Residue Studies for each Food Use	
Root and Tuber Vegetable Group	Monsanto wishes to maintain this crop grouping for preplant applications and therefore will collect all required residue data for turnips, potatoes and sugarbeets. We request the Agency clarify if data are required on radishes. Selective equipment residue work will not be conducted on Parsnips as this use will not be promoted. We request the Agency allow this crop grouping to remain intact in the 40 CFR until this residue data work is completed.
Leaves of Root and Tuber Vegetable Group	Monsanto wishes to maintain this crop grouping for pre-plant applications and therefore will collect the required residue data for turnip greens. We request the Agency allow this crop grouping to remain intact in the 40 CFR until this residue work is completed.
Bulb Vegetable Group	Will conduct onion residue studies.
Leafy Vegetables (except Brassica vegetables) Group	Monsanto wishes to maintain this crop grouping for preplant application and therefore will collect the required residue data for celery and spinach. We request the Agency allow this crop grouping to remain intact in the 40 CFR until this residue work is completed.
Brassica Leafy Vegetable Group	Monsanto wishes to maintain this crop grouping for preplant application and therefore will collect the required residue data for broccoli and mustard greens. We request the Agency allow this crop grouping to remain intact in the 40 CFR until this residue work is completed.

DATA REQUIREMENT	COMMENT/STATUS
Legume Vegetables (succulent or dried) Group	With the exception of soybeans, a crop grouping tolerance will be requested. The requested soybean soapstock data was submitted to the Agency in Monsanto's February 21, 1986 (RD 617) Preharvest Soybean petition; therefore, the soapstock data requirement submission has been completed.
Foliage of Legumes Vegetable Group	Except for soybean forage and hay, a crop group tolerance will be requested.
Fruiting Vegetables (except curcubits)	Since a crop group tolerance was set on 12/20/85 (FR Vol. 50, No. 245) no further action is required.
Cucurbits Vegetable Group	Since a crop group tolerance was set on 4/23/86 (FR Vol. 51, No. 78), no further action is required.
Citrus Fruits Group	Monsanto will clarify the calculations used to derive the whole fruit residues. Following that, we wish to meet with the Agency to determine if any additional residue work is required to maintain the citrus fruit group tolerances.
Stone Fruits Group	Monsanto elects not to do the required residue studies, but instead will change the labels to require a 17 day pre-harvest interval instead of the present 14 day interval. We assume that this will statisfy the Agency's concern in this area and request you concurrence. Concerning the requirement for processing studies in plums, we note that glyphosate when used in these plum orchards is applied as a directed spray to the base of the tree. No glyphosate is taken up by the tree, hence, residues are not detected. In order to obtain plums containing measurable levels of glyphosate the tree would have to be topically treated and would most certainly die. Therefore, it would make no sense to treat the tree in this manner, hence it will be impossible to conduct this processing study and we request tbe Agency delete this requirement.

DATA REQUIREMENT	COMMENT/STATUS
Small Fruits and Berries Group	A crop group tolerance was set on 4/23/86 (FR Vol. 51, No. 78). Monsanto will conduct a grape processing study. The Roundup wiper application use instructions for cranberries will be amended to allow only one wiper application within a 45-day preharvest interval; data in the original tolerance petition should support this label amendment.
Cereal Grain Group	Monsanto will request separate tolerances on corn, wheat, rice, barley and oats. Monsanto will submit field corn, grain sorghum and wheat processing residue data. Since the Agency approved on 5/28/86, the use of wiper equipment on sorghum (with a 40-day PHI), the requested 14-day PHI residue data are no longer necessary.
Forage, Fodder, and Straw-of--Cereal Grains Group	Since the Agency approved on May 28, 1986, the sorghum wiper application label with a restriction on feeding or grazing milo fodder, the 24(c) label should no longer be required. Separate tolerances will be requested for barley forage, hay and straw, corn forage, silage and fodder, oat forage, hay and straw, rice straw, sorghum forage, fodder, silage and hay and wheat forage, hay and straw.
Nongrass Animal Feeds (forage, fodder, straw, and hay) Group	Monsanto will collect the alfalfa seed processing data. Separate tolerances for residues on forage and hay of nongrass animal feeds will be requested.
Asparagus	We will agree to collect the required residue data.
Coffee	Monsanto will request approval from the Agency to amend the preharvest interval from 14-days to 28 days and we also request that the maximum rate on the label be reduced to a maximum annual rate/year of 2.0 lbs/acre a.e. which is the maximum now applied under use conditions. Therefore, we request that the requested coffee residue data (page 74) be deleted.

DATA REQUIREMENT	COMMENT/STATUS
Mangos	We agree to collect the required residue data.
Olives, processed and olive oil	The approved labels from Greece, Italy and Spain will be sent to the Agency. The olive-curing process will be submitted to the Agency.
Peanuts (forage, hay, hulls, meal, soapstock and oils)	Monsanto has withdrawn a petition to allow use of selective application equipment over peanuts. We are now agreeing to remove the label recommendation for spot treatment in peanuts. Hence, the only use for glyphosate in peanuts will be pre-plant. We therefore believe the processing data should now not be required since peanuts grown in glyphosate treated soil will not contain measurable levels of residues. We request the Agency's concurrence that these processing data are no longer required.
Pineapple forage	Monsanto will request the Agency to approve feeding and grazing restrictions for pineapple forage.
Sugarcane	Monsanto will request the Agency to approve a sugarcane forage grazing restriction.
Tea	Monsanto will request approval of a 7 ppm food additive tolerance for instant tea. Monsanto will provide the Agency with the requested foreign tea information and labels.
Irrigation Water	Refer to previous comments involving page 26 - item 17.

158.130 Environmental Fate

- Photodegradation
- Metabolism Studies - Lab
- Mobility Studies
- Dissipation Studies - Field
- Accumulation Studies

See basic discussion comments in Part E. When the Agency reviews the above information, we anticipate that they will concur with Monsanto that the additional studies are not required. If the Agency does not concur, we assume you will respond in adequate time for Monsanto to complete the studies within allotted timeframes for submission.

In the event that the Agency's review of this information makes it impossible for Monsanto to meet the suggested deadline, we will request to meet with the Agency to establish a new deadline.

TOXICOLOGY

Acute Testing 81-3 Acute Inhalation - Rat

There appears to be no justification for an acute inhalation study with glyphosate because a) People are not exposed to glyphosate. If any exposure does occur, it is either to the isopropylamine or sodium salts of glyphosate. Adequate inhalation toxicity studies have been or are being conducted with these end-use materials. The results of the available studies indicate a relatively low degree of acute inhalation toxicity. b) Glyphosate is a non-volatile solid material which is handled in manufacture [redacted] which precludes any inhalation exposure. Monsanto requests that this study no longer be required.

Chronic Testing

83-1 - Non-rodent (dog)

See basic discussion comments in Part C, page 8 - paragraph 2. The additional data was submitted to the Agency on August 11, 1986 as "Addendum to One-Year Toxicology Study in Dogs with Glyphosate" which addressed these issues.

83-2 Oncogenicity - Rat

Monsanto will conduct the repeat rat study. See basic discussion comments in Part C, page 8 - paragraph 1.

83-2 Oncogenicity - Mouse

See basic discussion comments in Part C (page 6 - paragraph 1, page 6 - paragraph 3, page 7 - paragraph 1) and Part D. When the Agency reviews the above information, we anticipate that they will concur with Monsanto that the additional mouse study is not required.

85-1 General Metabolism

See basic discussion comments in Part C, pages 10 and 11.

158.150 PLANT PROTECTION

- 122-1 - Seed germination/seedling emergence
- 122-1 - Vegetative Vigor
- 122-2 - Aquatic Plant Growth

The Agency is requiring that tier 1 testing be performed with glyphosate. Monsanto will respond within the Agency's allotted timeframe.

OCT 20 1986

Monsanto Company
1101 17th Street NW.
Washington, DC 20036

Attention: Thomas F. Armstrong

Gentlemen:

Subject: Shackle C Herbicide
EPA Registration No. 524-339
Re: Label Revision
Your Letter Dated June 11, 1986

The labeling referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act as amended, is acceptable. Please submit five (5) copies of your final printed labels incorporating this amendment. A stamped copy of labeling is enclosed for your record.

Sincerely yours,

Robert J. Taylor
Product Manager (25)
Fungicide-Herbicide Branch
Registration Division (TS-767C)

Enclosure

89579:Erumsele:T-5:KENCO:10/10/86:10/23/86:de:VO

CONCURRENCES

SYMBOL ▶	TS-767C							
SURNAME ▶	ERumsele							
DATE ▶	10-17-86							

EPA Form 1320-1 (4-81) OFFICIAL FILE COPY

Monsanto

Monsanto Company
1101 17th Street, N.W.
Washington, D.C. 20036
Phone: (202) 452-8880

June 11, 1986

Director
Registration Division (TS767C)
Office of Pesticide Programs
U. S. Environmental Protection Agency
1921 Jefferson Davis Highway
Crystal Mall #2, Room 716D
Arlington, Virginia 22202

Attention: Mr. Robert J. Taylor
Product Manager (25)

Subject: Shackle® C Herbicide
EPA Reg. No. 524-339
Stamped Labels Requested
- 54 Gallon Container Label
- Bulk Container Label

Dear Sir:

Shackle® C herbicide is registered (EPA Reg. No. 524-339) by the Agency solely for the purpose of reformulation by those companies permitted by Monsanto to manufacture a dilute glyphosate product. Roundup® herbicide is registered (EPA Reg. No. 524-308) by the Agency for use on many agricultural crops and for non-crop applications. The herbicide formulations in both of these two registrations are identical to each other.

At this time, Monsanto is submitting amended 54 gallon and bulk Shackle C container labels. To comply with P.R. Notice 83-3, the 54 gallon container label contains a revised Storage and Disposal statement that is appropriate for a plastic container. For both the 54 gallon and bulk container labels, the words "industrial, residential and ornamental areas" replaces the words "home lawns and gardens." Roundup is approved by the Agency for use in industrial, residential and ornamental areas, and we request the Agency approve these specific use areas for the Shackle C labels.

Enclosed for your use, are five (5) copies (includes one highlighted label) of each requested 54 gallon and bulk Shackle® C container labels. We request the Agency approve these labels as soon as possible.

If you have questions or comments about this registration request, please contact Lyle Gingerich or me.

Sincerely,

Tom Armstrong

Thomas F. Armstrong
Registration Manager

/pt
Enclosures

cc: L. L. Gingerich

LIMIT OF WARRANTY AND LIABILITY

This company warrants that this product conforms to the chemical description on this label. NO OTHER EXPRESS OR IMPLIED WARRANTY OF FITNESS FOR PARTICULAR PURPOSE OR MERCHANTABILITY IS MADE. This warranty is also subject to the conditions and limitations stated herein.

Buyer and all users shall promptly notify this company of any claims whether based in contract, negligence, strict liability, other tort or otherwise.

Buyer and all users are responsible for all loss or damage from use or handling which results from conditions beyond the control of this company, including but not limited to uses or applications in any manner not explicitly set forth in this label or application to or contact with desirable vegetation.

THE EXCLUSIVE REMEDY OF THE USER OR BUYER, AND THE LIMIT OF THE LIABILITY OF THIS COMPANY OR ANY OTHER SELLER FOR ANY AND ALL LOSSES, INJURIES OR DAMAGES RESULTING FROM THE USE OR HANDLING OF THIS PRODUCT (INCLUDING CLAIMS BASED IN CONTRACT, NEGLIGENCE, STRICT LIABILITY, OTHER TORT OR OTHERWISE) SHALL BE THE PURCHASE PRICE PAID BY THE USER OR BUYER FOR THE QUANTITY OF THIS PRODUCT INVOLVED, OR, AT THE ELECTION OF THIS COMPANY OR ANY OTHER SELLER, THE REPLACEMENT OF SUCH QUANTITY OR, IF NOT ACQUIRED BY PURCHASE, REPLACEMENT OF SUCH QUANTITY. IN NO EVENT SHALL THIS COMPANY OR ANY OTHER SELLER BE LIABLE FOR ANY INCIDENTAL OR CONSEQUENTIAL DAMAGES.

The buyer and all users are deemed to have accepted the terms of this LIMIT OF WARRANTY AND LIABILITY which may not be varied by any verbal or written agreement.

MONSANTO COMPANY
AGRICULTURAL PRODUCTS
ST. LOUIS, MISSOURI 63167 U.S.A.

MAP-2233.08/53F

PRECAUTIONARY STATEMENTS

Hazards to Humans and Domestic Animals

Keep out of reach of children.

WARNING!

CAUSES EYE IRRITATION.
HARMFUL IF SWALLOWED.
MAY CAUSE SKIN IRRITATION.
Do not get in eyes, on skin or on clothing.
Wash thoroughly after handling.

FIRST AID: IF IN EYES, immediately flush with plenty of water for at least 15 minutes. Call a physician.

IF ON SKIN, immediately flush with plenty of water. Remove contaminated clothing. Wash clothing before reuse.

IF SWALLOWED, this product will cause gastrointestinal tract irritation. Immediately dilute by swallowing water or milk. Call a physician.

In case of an emergency involving this product, Call Collect, day or night (314) 694-4000.

Environmental Hazards

Keep out of lakes, streams and ponds. Do not contaminate water by disposal of waste or cleaning of equipment.

Physical or Chemical Hazards

Solutions of this product should be mixed and stored only in stainless steel, aluminum, fiberglass, plastic and plastic-lined steel containers.

DO NOT MIX OR STORE THIS PRODUCT OR SOLUTIONS OF THIS PRODUCT IN GALVANIZED STEEL OR UNLINED STEEL (EXCEPT STAINLESS STEEL) CONTAINERS OR SPRAY TANKS.

This product or solutions of this product react with such containers and tanks to produce hydrogen gas which may form a highly combustible gas mixture. This gas mixture could flash or explode, causing serious personal injury, if ignited by open flame, spark, welder's torch, lighted cigarette, or other ignition source.

Storage and Disposal

Do not contaminate water, foodstuffs, seed or feed by storage or disposal.

DISPOSAL:
Wastes resulting from the use of this product that cannot be used or chemically reprocessed should be disposed of in a landfill approved for pesticide disposal or buried on site in a safe place away from water supplies. All disposal should be in accordance with applicable Federal, state or local procedures.

Emptied container retains vapor and product residue. Observe all labeled safeguards until container is cleaned, reconditioned or destroyed. DO NOT CUT OR WELD ON OR NEAR THIS CONTAINER.

Do not reuse container. Triple rinse container. Then puncture and dispose of in a sanitary landfill, or by incineration, or, if allowed by state and local authorities, by burning. If burned, stay out of smoke.

1274

CONCENTRATE

SHACKLE® C

HERBICIDE BY **Monsanto**

For formulation of products (not to exceed 10% active ingredient) for weed and grass control in industrial, residential and ornamental areas.

It is a violation of Federal Law to use this product in any manner inconsistent with its labeling.

Read the entire label before using this product.

Read "LIMIT OF WARRANTY AND LIABILITY" before buying or using. If terms are not acceptable, return at once unopened.

Keep out of reach of children.

WARNING! Read precautions on side panel.

In case of an emergency involving this product, Call Collect, day or night, (314) 694-4000.

ACTIVE INGREDIENT:	
*Isopropylamine salt of glyphosate	41.0%
INERT INGREDIENTS:	59.0%
	100.0%

*Contains 480 grams per liter or 4 pounds of the active ingredient isopropylamine salt of N-(phosphonomethyl) glycine per U.S. gallon. Equivalent to 356 grams per liter or 3 pounds per U.S. gallon of the acid, glyphosate.

EPA Reg. No. 524-339

EPA Est. No. 524-NC-1

NET 54 U.S. GAL.

LIMIT OF WARRANTY AND LIABILITY

This company warrants that this product conforms to the chemical description on this label. NO OTHER EXPRESS OR IMPLIED WARRANTY OF FITNESS FOR PARTICULAR PURPOSE OR MERCHANTABILITY IS MADE. This warranty is also subject to the conditions and limitations stated herein.

Buyer and all users shall promptly notify this company of any claims whether based in contract, negligence, strict liability, other tort or otherwise.

Buyer and all users are responsible for all loss or damage from use or handling which results from conditions beyond the control of this company, including but not limited to uses or applications in any manner not explicitly set forth in this label or application to or contact with desirable vegetation.

THE EXCLUSIVE REMEDY OF THE USER OR BUYER, AND THE LIMIT OF THE LIABILITY OF THIS COMPANY OR ANY OTHER SELLER FOR ANY AND ALL LOSSES, INJURIES OR DAMAGES RESULTING FROM THE USE OR HANDLING OF THIS PRODUCT (INCLUDING CLAIMS BASED IN CONTRACT, NEGLIGENCE, STRICT LIABILITY, OTHER TORT OR OTHERWISE) SHALL BE THE PURCHASE PRICE PAID BY THE USER OR BUYER FOR THE QUANTITY OF THIS PRODUCT INVOLVED, OR, AT THE ELECTION OF THIS COMPANY OR ANY OTHER SELLER, THE REPLACEMENT OF SUCH QUANTITY OR, IF NOT ACQUIRED BY PURCHASE, REPLACEMENT OF SUCH QUANTITY. IN NO EVENT SHALL THIS COMPANY OR ANY OTHER SELLER BE LIABLE FOR ANY INCIDENTAL OR CONSEQUENTIAL DAMAGES.

The buyer and all users are deemed to have accepted the terms of this LIMIT OF WARRANTY AND LIABILITY which may not be varied by any verbal or written agreement.

MONSANTO COMPANY
AGRICULTURAL PRODUCTS
ST. LOUIS, MISSOURI 63167 U.S.A.

MAP-2233.09/53F

PRECAUTIONARY STATEMENTS

Hazards to Humans and Domestic Animals

Keep out of reach of children.

WARNING!

CAUSES EYE IRRITATION.
HARMFUL IF SWALLOWED.
MAY CAUSE SKIN IRRITATION.
Do not get in eyes, on skin or on clothing.
Wash thoroughly after handling.

FIRST AID: IF IN EYES, immediately flush with plenty of water for at least 15 minutes. Call a physician.

IF ON SKIN, immediately flush with plenty of water. Remove contaminated clothing. Wash clothing before reuse.

IF SWALLOWED, this product will cause gastrointestinal tract irritation. Immediately dilute by swallowing water or milk. Call a physician.

In case of an emergency involving this product, Call Collect, day or night (314) 694-4000.

Environmental Hazards

Keep out of lakes, streams and ponds. Do not contaminate water by disposal of waste or cleaning of equipment.

Physical or Chemical Hazards

Solutions of this product should be mixed and stored only in stainless steel, aluminum, fiberglass, plastic and plastic-lined steel containers.

DO NOT MIX OR STORE THIS PRODUCT OR SOLUTIONS OF THIS PRODUCT IN GALVANIZED STEEL OR UNLINED STEEL (EXCEPT STAINLESS STEEL) CONTAINERS OR SPRAY TANKS.

This product or solutions of this product react with such containers and tanks to produce hydrogen gas which may form a highly combustible gas mixture. This gas mixture could flash or explode, causing serious personal injury, if ignited by open flame, spark, welder's torch, lighted cigarette, or other ignition source.

Storage and Disposal

Do not contaminate water, foodstuffs, seed or feed by storage or disposal.

DISPOSAL:
Wastes resulting from the use of this product that cannot be used or chemically reprocessed should be disposed of in a landfill approved for pesticide disposal or buried on site in a safe place away from water supplies. All disposal should be in accordance with applicable Federal, state or local procedures.

Emptied container retains vapor and product residue. Observe all labeled safeguards until container is cleaned, reconditioned or destroyed. DO NOT CUT OR WELD ON OR NEAR THIS CONTAINER.

Triple rinse emptied bulk containers. Then offer for recycling or reconditioning, or dispose of in a manner approved by state and local authorities.

CONCENTRATE

SHACKLE® C

HERBICIDE BY **Monsanto**

For formulation of products (not to exceed 10% active ingredient) for weed and grass control in industrial, residential and ornamental areas.

It is a violation of Federal Law to use this product in any manner inconsistent with its labeling.

Read the entire label before using this product.

Read "LIMIT OF WARRANTY AND LIABILITY" before buying or using. If terms are not acceptable, return at once unopened.

Keep out of reach of children.

WARNING! Read precautions on side panel.

In case of an emergency involving this product, Call Collect, day or night, (314) 694-4000.

ACTIVE INGREDIENT:	
*Isopropylamine salt of glyphosate	41.0%
INERT INGREDIENTS:	59.0%
	100.0%

*Contains 480 grams per liter or 4 pounds of the active ingredient isopropylamine salt of N-(phosphonomethyl) glycine per U.S. gallon. Equivalent to 356 grams per liter or 3 pounds per U.S. gallon of the acid, glyphosate.

EPA Reg. No. 524-339

EPA Est. No. 524-NC-1

NET _____ U.S. GAL.

OMB Approval No. 2000-0468

FIFRA SECTION 3(C)(2)(B) SUMMARY SHEET	EPA REGISTRATION NO. 524-339

PRODUCT NAME: Shackle® C Herbicide

APPLICANT'S NAME	DATE GUIDANCE DOCUMENT ISSUED
Monsanto Company	August 11, 1986

With respect to the requirement to submit "generic" data imposed by the FIFRA section 3(C)(2)(B) notice contained in the referenced Guidance Document, I am responding in the following manner:

☒ 1. I will submit data in a timely manner to satisfy the following requirements. If the test procedures I will use deviate from (or are not specified in) the Registration Guidelines or the Protocols contained in the Reports of Expert Groups to the Chemicals Group, OECD Chemicals Testing Programme, I enclose the protocols that I will use:

☐ 2. I have entered into an agreement with one or more other registrants under FIFRA section 3(C)(2)(B)(ii) to satisfy the following data requirements. The tests, and any required protocols, will be submitted to EPA by:

NAME OF OTHER REGISTRANT

☐ 3. I enclose a completed "Certification of Attempt to Enter Into an Agreement with Other Registrants for Development of Data" with respect to the following data requirements:

☐ 4. I request that you amend my registration by deleting the following uses (this option is not available to applicants for new products):

☐ 5. I request voluntary cancellation of the registration of this product. (This option is not available to applicants for new products.)

REGISTRANT'S AUTHORIZED REPRESENTATIVE	SIGNATURE	DATE
Thomas F. Armstrong	Thomas F. Armstrong	11/7/86

EPA Form 8580-1 (10-82)

007 203

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

CERTIFIED MAIL

Monsanto Representative picked up August 11, 1986

AUG 11 1986

OFFICE OF PESTICIDES AND TOXIC SUBSTANCES

Monsanto Company
1101 17th Street N.W.
Washington, D. C. 20036

SUBJECT: Initiation of Reregistration Process for Pesticide Products Containing Glyphosate as the Single Active Ingredient

Dear Registrant:

In accordance with the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, EPA's Office of Pesticide Programs has begun the reregistration process for pesticide products containing the subject ingredient. Significant changes to the statute were made in 1972, 1975, and 1978; thus, current requirements may be substantially different from those in effect at the time your product(s) were registered. The first phase of reregistration requires that you (1) make a commitment to the Agency regarding data development and (2) subsequently submit revised product labeling and associated information.

This mailing contains the Guidance Document for preparation of submissions, as well as a listing of your affected product(s) (Attachment A), and a separate list of registrants with products subject to this standard and which contain this active ingredient (Attachment B). The latter list is for the purpose of cooperative data development.

The Guidance Document sets out the Agency's evaluation of all available data pertaining to the subject chemical and its registered uses, and its rationale for the regulatory actions being taken at this time. Additionally, the Guidance Document contains instructions describing certain of the steps you must take to maintain registration for your product(s). Products not brought into compliance with the Guidance Document will be subject to suspension and/or cancellation.

Specifically, the enclosed Guidance Document does the following:

1. Introduces the purpose of this document.

2. Explains the Agency's policy regarding data submission and identifies, in table format, the data that must be submitted to complete the Agency's evaluation of each product. In addition, a bibliography identifying the data which is considered part of the data base supporting the registration standard is included.

3. Sets out time-frames for submission of required data.

4. Explains how to revise labeling for manufacturing use products.

5. Provides submission instructions.

Because of the variety and complexity of the requirements, and the short statutory timeframes available for certain actions, it is essential that you understand the specific requirements and procedures in order that you may respond in a correct and timely manner. Since a part of these requirements is under Section 3(c)(2)(B) of FIFRA, your first response may be required within 90 days from receipt of this letter. Please note that <u>if you do not respond or do not comply fully with the requirements, your application may be rejected or your product registration cancelled or suspended</u>.

If, after reviewing this material, you do not understand what you must do or how or when you must respond, please contact the Product Manager listed below who will assist you in every reasonable way. If you wish to discuss the data requirements or request that certain data be waived, you must write to the Agency and indicate those data requirements with which you take issue and your rationale for doing so. After the Agency has had a chance to review your submission, the Product Manager will contact you to set up a meeting for the purpose of resolving all issues relative to data requirements.

If you have any questions concerning this Guidance Document, you may contact the Product Manager listed below:

Robert J. Taylor
Product Manager 25
Registration Division (TS-767)
Office of Pesticide Programs
Environmental Protection Agency
Washington, D.C. 20460
Telephone 703/557-1800

Sincerely,

James Akerman, Acting Director
Registration Division (TS-767)

Enclosure

ATTACHMENT A

PRODUCTS AFFECTED BY THIS
REREGISTRATION PROCESS

Following is a list of your products affected by this reregistration process. If this list is incomplete or inaccurate in any way, please notify the Product Manager (PM) identified in the letter.

EPA Registration Number	Product Name
524-333	MON-0139 62% Solution
524-339	Shackle C
524-370	Roundup L&G
524-318	MON 0139 Technical Solution (53.5)

ATTACHMENT B

REGISTRANTS WITH PESTICIDE PRODUCTS CONTAINING
THE ACTIVE INGREDIENT

The information attached will allow registrants with pesticide products containing the above ingredient to contact one another regarding joint data development or sharing the cost of data development under section 3(c)(2)(B) of FIFRA. This information includes the following: EPA Reg. No., company name, company address, active ingredient, percentage of active ingredient and type of formulation, such as Manufacturing-Use Product (MP), Technical Product (TP), Wettable Powder (WP), and Emulsifiable Concentrate (EC).

JAN 28 1986

Monsanto Company
1101 17th Street NW.
Washington, DC 20036

Attention: Thomas F. Armstrong

Gentlemen:

Subject: Shackle C Herbicide (Revise 54 Gallon Container Label and Bulk Container Label)
EPA Registration No. 524-339
Your Letter of November 11, 1985

The labeling referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, is acceptable. A stamped copy is enclosed for your records.

Sincerely yours,

Robert J. Taylor
Product Manager (25)
Fungicide-Herbicide Branch
Registration Division (TS-767C)

Enclosure

92694:Taylor:T-2:KENCO:1/23/86:1/31/86:TAR:MD

CONCURRENCES

SYMBOL ▶	TS-767C							
SURNAME ▶	VKWalker							
DATE ▶	1/28/86							

EPA Form 1320-1 (4-81)

OFFICIAL FILE COPY

CONCENTRATE

SHACKLE® C

HERBICIDE BY **Monsanto**

ACCEPTED

JAN 2 8 1986

Under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, for the pesticide registered under EPA Reg. No. 524-339

For formulation of products (not to exceed 10% active ingredient) for weed and grass control in home lawns and gardens.

It is a violation of Federal Law to use this product in any manner inconsistent with its labeling.

Read the entire label before using this product.

Read "LIMIT OF WARRANTY AND LIABILITY" before buying or using. If terms are not acceptable, return at once unopened.

Keep out of reach of children.

WARNING! Read precautions on side panel.

ACTIVE INGREDIENT:	
*Isopropylamine salt of glyphosate	41.0%
INERT INGREDIENTS:	59.0%
	100.0%

*Contains 480 grams per liter or 4 pounds of the active ingredient isopropylamine salt of N-(phosphonomethyl) glycine per U.S. gallon.

Equivalent to 356 grams per liter or 3 pounds per U.S. gallon of the acid, glyphosate.

EPA Reg. No. 524-339

EPA Est. No. 524-LA-1

In case of an emergency involving this product, Call Collect, day or night, (314) 694-4000.

NET 54 U.S. GAL.

LIMIT OF WARRANTY AND LIABILITY

This company warrants that this product conforms to the chemical description on this label. NO OTHER EXPRESS OR IMPLIED WARRANTY OF FITNESS FOR PARTICULAR PURPOSE OR MERCHANTABILITY IS MADE. This warranty is also subject to the conditions and limitations stated herein.

Buyer and all users shall promptly notify this company of any claims whether based in contract, negligence, strict liability, other tort or otherwise.

Buyer and all users are responsible for all loss or damage from use or handling which results from conditions beyond the control of this company, including but not limited to uses or applications in any manner not explicitly set forth in this label or application to or contact with desirable vegetation.

THE EXCLUSIVE REMEDY OF THE USER OR BUYER, AND THE LIMIT OF THE LIABILITY OF THIS COMPANY OR ANY OTHER SELLER FOR ANY AND ALL LOSSES, INJURIES OR DAMAGES RESULTING FROM THE USE OR HANDLING OF THIS PRODUCT (INCLUDING CLAIMS BASED IN CONTRACT, NEGLIGENCE, STRICT LIABILITY, OTHER TORT OR OTHERWISE) SHALL BE THE PURCHASE PRICE PAID BY THE USER OR BUYER FOR THE QUANTITY OF THIS PRODUCT INVOLVED, OR, AT THE ELECTION OF THIS COMPANY OR ANY OTHER SELLER, THE REPLACEMENT OF SUCH QUANTITY OR, IF NOT ACQUIRED BY PURCHASE, REPLACEMENT OF SUCH QUANTITY. IN NO EVENT SHALL THIS COMPANY OR ANY OTHER SELLER BE LIABLE FOR ANY INCIDENTAL OR CONSEQUENTIAL DAMAGES.

The buyer and all users are deemed to have accepted the terms of this LIMIT OF WARRANTY AND LIABILITY which may not be varied by any verbal or written agreement.

(2)

U.S. Pat. No. 3,799,758 and U.S. Pat. No. 4,405,531 covers use. Other patents are pending.

® Shackle is a registered trademark of Monsanto Company

MONSANTO COMPANY
AGRICULTURAL PRODUCTS
ST. LOUIS, MISSOURI 63167 U.S.A.

Monsanto

MAP-2233.05/53L

(3)

PRECAUTIONARY STATEMENTS

Hazards to Humans and Domestic Animals

Keep out of reach of children.

WARNING!

CAUSES EYE IRRITATION.
HARMFUL IF SWALLOWED.
MAY CAUSE SKIN IRRITATION.
Do not get in eyes, on skin or on clothing.
Wash thoroughly after handling.

FIRST AID: IF IN EYES, immediately flush with plenty of water for at least 15 minutes. Call a physician.

IF ON SKIN, immediately flush with plenty of water. Remove contaminated clothing. Wash clothing before reuse.

IF SWALLOWED, this product will cause gastrointestinal tract irritation. Immediately dilute by swallowing water or milk. Call a physician.

In case of an emergency involving this product, Call Collect, day or night (314) 694-4000.

Environmental Hazards

Keep out of lakes, streams and ponds. Do not contaminate water by disposal of waste or cleaning of equipment.

Physical or Chemical Hazards

Solutions of this product should be mixed and stored only in stainless steel, aluminum, fiberglass, plastic and plastic-lined steel containers.

DO NOT MIX OR STORE THIS PRODUCT OR SOLUTIONS OF THIS PRODUCT IN GALVANIZED STEEL OR UNLINED STEEL (EXCEPT STAINLESS STEEL) CONTAINERS OR SPRAY TANKS.

This product or solutions of this product react with such containers and tanks to produce hydrogen gas which may form a highly combustible gas mixture. This gas mixture could flash or explode, causing serious personal injury, if ignited by open flame, spark, welder's torch, lighted cigarette, or other ignition source.

Storage and Disposal

(3)

Do not contaminate water, foodstuffs, seed or feed by storage or disposal.

DISPOSAL:
Wastes resulting from the use of this product that cannot be used or chemically reprocessed should be disposed of in a landfill approved for pesticide disposal or buried on site in a safe place away from water supplies. All disposal should be in accordance with applicable Federal, state or local procedures.

Emptied container retains vapor and product residue. Observe all labeled safeguards until container is cleaned, reconditioned or destroyed. DO NOT CUT OR WELD ON OR NEAR THIS CONTAINER.

Triple rinse emptied container. Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or by other procedures approved by state and local authorities.

CONCENTRATE

SHACKLE® C

HERBICIDE BY **Monsanto**

ACCEPTED

JAN 2 8 1986

Under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, for the pesticide registered under EPA Reg. No. 524-339

For formulation of products (not to exceed 10% active ingredient) for weed and grass control in home lawns and gardens.

It is a violation of Federal Law to use this product in any manner inconsistent with its labeling.

Read the entire label before using this product.

Read "LIMIT OF WARRANTY AND LIABILITY" before buying or using. If terms are not acceptable, return at once unopened.

Keep out of reach of children.

WARNING! *Read precautions on side panel.*

ACTIVE INGREDIENT:	
*Isopropylamine salt of glyphosate	41.0%
INERT INGREDIENTS:	59.0%
	100.0%

*Contains 480 grams per liter or 4 pounds of the active ingredient isopropylamine salt of N-(phosphonomethyl) glycine per U.S. gallon.

Equivalent to 356 grams per liter or 3 pounds per U.S. gallon of the acid, glyphosate.

EPA Reg. No. 524-339

EPA Est. No. 524-LA-1

In case of an emergency involving this product, Call Collect, day or night, (314) 694-4000.

NET U.S. GAL.

LIMIT OF WARRANTY AND LIABILITY

This company warrants that this product conforms to the chemical description on this label. NO OTHER EXPRESS OR IMPLIED WARRANTY OF FITNESS FOR PARTICULAR PURPOSE OR MERCHANTABILITY IS MADE. This warranty is also subject to the conditions and limitations stated herein.

Buyer and all users shall promptly notify this company of any claims whether based in contract, negligence, strict liability, other tort or otherwise.

Buyer and all users are responsible for all loss or damage from use or handling which results from conditions beyond the control of this company, including but not limited to uses or applications in any manner not explicitly set forth in this label or application to or contact with desirable vegetation.

THE EXCLUSIVE REMEDY OF THE USER OR BUYER, AND THE LIMIT OF THE LIABILITY OF THIS COMPANY OR ANY OTHER SELLER FOR ANY AND ALL LOSSES, INJURIES OR DAMAGES RESULTING FROM THE USE OR HANDLING OF THIS PRODUCT (INCLUDING CLAIMS BASED IN CONTRACT, NEGLIGENCE, STRICT LIABILITY, OTHER TORT OR OTHERWISE) SHALL BE THE PURCHASE PRICE PAID BY THE USER OR BUYER FOR THE QUANTITY OF THIS PRODUCT INVOLVED, OR, AT THE ELECTION OF THIS COMPANY OR ANY OTHER SELLER, THE REPLACEMENT OF SUCH QUANTITY OR, IF NOT ACQUIRED BY PURCHASE, REPLACEMENT OF SUCH QUANTITY. IN NO EVENT SHALL THIS COMPANY OR ANY OTHER SELLER BE LIABLE FOR ANY INCIDENTAL OR CONSEQUENTIAL DAMAGES.

The buyer and all users are deemed to have accepted the terms of this LIMIT OF WARRANTY AND LIABILITY which may not be varied by any verbal or written agreement.

(2)

U.S. Pat. No. 3,799,758 and U.S. Pat. No. 4,405,531 covers use. Other patents are pending.

® Shackle is a registered trademark of Monsanto Company

MONSANTO COMPANY
AGRICULTURAL PRODUCTS
ST. LOUIS, MISSOURI 63167 U.S.A.

Monsanto

MAP-2233.04/53L

PRECAUTIONARY STATEMENTS

(3)

Hazards to Humans and Domestic Animals

Keep out of reach of children.

WARNING!

CAUSES EYE IRRITATION.
HARMFUL IF SWALLOWED.
MAY CAUSE SKIN IRRITATION.
Do not get in eyes, on skin or on clothing.
Wash thoroughly after handling.

FIRST AID: IF IN EYES, immediately flush with plenty of water for at least least 15 minutes. Call a physician.

IF ON SKIN, immediately flush with plenty of water. Remove contaminated clothing. Wash clothing before reuse.

IF SWALLOWED, this product will cause gastrointestinal tract irritation. Immediately dilute by swallowing water or milk. Call a physician.

In case of an emergency involving this product, Call Collect, day or night (314) 694-4000.

Environmental Hazards

Keep out of lakes, streams and ponds. Do not contaminate water by disposal of waste or cleaning of equipment.

Physical or Chemical Hazards

Solutions of this product should be mixed and stored only in stainless steel, aluminum, fiberglass, plastic and plastic-lined steel containers.

DO NOT MIX OR STORE THIS PRODUCT OR SOLUTIONS OF THIS PRODUCT IN GALVANIZED STEEL OR UNLINED STEEL (EXCEPT STAINLESS STEEL) CONTAINERS OR SPRAY TANKS.

This product or solutions of this product react with such containers and tanks to produce hydrogen gas which may form a highly combustible gas mixture. This gas mixture could flash or explode, causing serious personal injury, if ignited by open flame, spark, welder's torch, lighted cigarette, or other ignition source.

Storage and Disposal

(3)

Do not contaminate water, foodstuffs, seed or feed by storage or disposal.

DISPOSAL:
Wastes resulting from the use of this product that cannot be used or chemically reprocessed should be disposed of in a landfill approved for pesticide disposal or buried on site in a safe place away from water supplies. All disposal should be in accordance with applicable Federal, state or local procedures.

Emptied container retains vapor and product residue. Observe all labeled safeguards until container is cleaned, reconditioned or destroyed. DO NOT CUT OR WELD ON OR NEAR THIS CONTAINER.

Triple rinse emptied bulk container. Then offer for recycling or reconditioning, or dispose of in a manner approved by state and local authorities.

SUBMISSION REVIEW RECORD

G

1. REGISTRATION NUMBER	CYCLE	2. DATE RECEIVED (MO / DAY / YR)
524-333		01 / 19 / 85

3. 3CID PUBLICATION NECESSARY	4. PETITION NO.	5. RECEIVED PM TEAM (MO / DAY / YR)
☐ YES ☐ NO		

6. METHOD OF SUPPORT	7. PRODUCT MANAGER	NO.	8. PROJECTED RETURN (MO / DAY / YR)
☐ 2A ☐ 2B ☐ 2C			

9. DATE PULLED	10. DATE PUBLISHED	11. ACTION TYPE	CODE	12. OUTGOING DATE (MO / DAY / YR)
1/21/86		Update 54gal & Bulk Container Label R446 30P		

REV. SEQ.	REVIEW TYPE CODE	REVIEW TYPE	REVIEWER CODE (Initials)	SIGNATURE OF REVIEWER	COMMENT CODE	DATE REVIEW COMPLETED (MO / DAY / YR)
	A	REVIEWABILITY TEAM				
	B	PRODUCT MANAGER TEAM EFFICACY REVIEW				
	C	PRODUCT MANAGER TEAM HUMAN SAFETY REVIEW				
	D	PRODUCT MANAGER TEAM ENVIRONMENTAL SAFETY REVIEW				
	E	PRODUCT MANAGER TEAM RESUBMISSION REVIEW				
	F	PRODUCT MANAGER		UKW	NAC	01 / 21 / 86
	G	INTERAGENCY REFERRAL				
	H	COST-BENEFIT REVIEW				
	I	PUBLIC COMMENTS REVIEW				
	J	EEE BRANCH INSECTICIDE EFFICACY				
	K	EEE BRANCH HERBICIDE EFFICACY				
	L	EEE BRANCH FUNGICIDE EFFICACY				
	M	EEE BRANCH RODENTICIDE EFFICACY				
	N	EEE BRANCH DISINFECTANT EFFICACY				
	O	CHEMISTRY BRANCH RESIDUE CHEMISTRY				
	P	EEE BRANCH ENVIRONMENTAL CHEMISTRY				
	Q	TOXICOLOGY BRANCH HUMAN SAFETY				
	R	EEE BRANCH ENVIRONMENTAL SAFETY				
	S					
	T					

PRODUCT MANAGER SIGNATURE	TYPE OF RESPONSE	CODE

EPA Form 8570-13 (3-78)

Monsanto

Monsanto Company
1101 17th Street, N.W.
Washington, D.C. 20036
Phone: (202) 452-8880
November 11, 1985

Director
Registration Division (TS767C)
Office of Pesticide Programs
U. S. Environmental Protection Agency
1921 Jefferson Davis Highway
Crystal Mall #2, Room 716D
Arlington, Virginia 22202

Attention: Mr. Robert J. Taylor
Product Manager (25)

Subject: Shackle® C Herbicide
EPA Reg. No. 524-339
Stamped Labels Requested
- 54 Gallon Container Label
- Bulk Container Label

Dear Sir:

Shackle® C herbicide is registered (EPA Reg. No. 524-339) by the Agency solely for the purpose of reformulation by those companies permitted by Monsanto to manufacture a dilute glyphosate product. Roundup® herbicide is registered (EPA Reg. No. 524-308) by the Agency for use on many agricultural crops and for non-crop applications. The herbicide formulations in both of these two registrations are identical to each other.

At this time, Monsanto is submitting amended 54 gallon and bulk Shackle C container labels. These revised Shackle C labels contain updated precautionary statements, first aid statements, and editorial changes to agree with the currently approved Roundup container labeling.

For the 54 gallon and bulk container labels, attached are highlighted copies of these requested labels (numbers correspond to numbers on the attached labels):

1. The words "before using this product" have been added.

2. The U.S. Pat. No. 4,405,531 has been added.

3. The Precautionary Statements for "Hazards to Humans and Domestic Animals" and "Storage and Disposal" have been updated to contain the approved Roundup label terminology.

Enclosed for your use, are five (5) copies (includes one highlighted label) of each requested 54 gallon and bulk Shackle® C container labels. We request the Agency approve these labels as soon as possible.

If you have questions or comments about this registration request, please contact Lyle Gingerich or me.

Sincerely,

Tom Armstrong

Thomas F. Armstrong
Registration Manager

/pt
Enclosures

cc: L. L. Gingerich

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

NOV 18 1985

Monsanto Company
1101 17th Street NW.
Washington, DC 20036

yellow copy

Attention: Thomas F. Armstrong

Gentlemen:

Subject: Roundup Herbicide (Additional Information on Mouse Oncogenicity Study)
EPA Registration No. 524-308
Shackle
EPA Registration No. 524-330
Polado Plant Growth Regulator
EPA Registration No. 524-332
Shackle C
EPA Registration No. 524-339
Rodeo Herbicide
EPA Registration No. 524-343
Landmaster Herbicide
EPA Registration No. 524-351
Your Letter of October 28, 1985

We have your letter of October 28, 1985 transmitting an addendum to the mouse study in support of the subject registrations. Further action will await completion of scientific review and evaluations.

The accession number assigned the data is 260023.

Sincerely yours,

VEW

Robert J. Taylor
Product Manager (25)
Fungicide-Herbicide Branch
Registration Division (TS-767C)

Monsanto

Monsanto Company
1101 17th Street, N.W.
Washington, D.C. 20036
Phone: (202) 452-8860
October 28, 1985

Director
Registration Division (TS767C)
Office of Pesticide Programs
U. S. Environmental Protection Agency
1921 Jefferson Davis Highway
Crystal Mall #2, Room 716D
Arlington, Virginia 22202

Attention: Mr. Robert J. Taylor
Product Manager (25)

Subject: Roundup® Herbicide
EPA Reg. Nos.
524-308, 524-330, 524-332,
524-339, 524-343, 524-351
Addendum to Chronic Mouse
Study with Glyphosate
• Additional Evaluations

Dear Sir:

On July 21, 1983, Monsanto submitted a glyphosate chronic mouse study entitled "A Chronic Feeding Study Of Glyphosate (Roundup® Technical) In Mice (R.D. No. 480 and accession numbers 251007-251014). Subsequently, on July 29, 1985, the Agency requested Monsanto to recut the male mouse kidneys to obtain further information on the presence or absence of kidney tumors. This additional work was completed and submitted on October 7, 1985 to the Agency (R.D. No. 635). It is important to note that these additional data confirm Monsanto's initial position of no treatment related oncogenic effects.

Due to the importance of this chronic mouse study to Monsanto, we requested noted experts (4 individual experts and a consultant panel) to also review these data. They were requested to determine if the effects observed could be considered to be a treatment related oncogenic effect. The conclusions reached by these experts are now being submitted (R.D. No. 643) for Agency information and file use.

The review results from the independent evaluations of the glyphosate chronic mouse study are the same. Their conclusion is the data reveals no statistically significant difference between any of the treated and control groups, and no statistically significant trend is present.

Based on this information and the previously submitted information which demonstrated that glyphosate did not show a treatment-related oncogenic effect in this chronic mouse study, Monsanto is hopeful that the Agency will reach the same conclusion. In addition, we request that the review of all pending glyphosate petitions now be completed as soon as possible.

Sincerely,

Tom Armstrong

Thomas F. Armstrong
Registration Manager

/pt
Enclosures

cc: L. L. Gingerich

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

Monsanto Company
1101 17th Street NW.
Washington, DC 20036

yellow copy NOV 18 1985

Attention: Robert W. Street

Gentlemen:

Subject: Roundup Herbicide (One-Year Dog Study)
EPA Registration No. 524-308
Shackle
EPA Registration No. 524-330
Polado Plant Growth Regulator
EPA Registration No. 524-332
Shackle C
EPA Registration No. 524-339
Rodeo Herbicide
EPA Registration No. 524-343
Landmaster Herbicide
EPA Registration No. 524-351
Your Letter of October 17, 1985

We have your letter of October 17, 1985 transmitting a one-year dog study in support of the subject registrations. Further action will await completion of scientific review and evaluation.

The accession number assigned these data is 260021.

Sincerely yours,

VICW

Robert J. Taylor
Product Manager (25)
Fungicide-Herbicide Branch
Registration Division (TS-767C)

Monsanto

Monsanto Company
1101 17th Street, N.W.
Washington, D.C. 20036
Phone: (202) 452-8860

October 17, 1985

Director
Registration Division (TS767C)
Office of Pesticide Programs
U.S. Environmental Protection Agency
1921 Jefferson Davis Highway
Arlington, Virginia 22201

Attention: Mr. Robert J. Taylor
Product Manager (25)

SUBJECT: Roundup® Herbicide, Rodeo® Herbicide, Landmaster® Herbicide, Shackle® Herbicide, Shackle®C Herbicide, and Polado Plant Growth Regulator, EPA Reg. Nos. 524-308, 524-330, 524-351, 524-339, 524-332, 524-343.

Submission of a One-Year Toxicology Study in Dogs with Glyphosate.

260021

Dear Sir:

At this time, Monsanto Company submits the final report of a toxicology study titled: "Twelve Month Study of Glyphosate Administered by Gelatin Capsule to Beagle Dogs." This report is submitted in one volume designated RD #636, MSL 5069, and dated October 17, 1985. This study replaces a two-year study conducted by Industrial Biotest Laboratory and ruled invalid by the EPA on August 10, 1982.

Please inform us of the accession number assigned to this submission.

Sincerely,

Robert W. Street
Manager, Product Health and Safety Information

/ss

cc: L. L. Gingerich

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

Monsanto Company
1101 17th Street NW.
Washington, DC 20036

yellow copy

NOV 18 1985

Attention: Thomas F. Armstrong

Gentlemen:

Subject: Roundup Herbicide (Product Chemistry Data)
EPA Registration No. 524-308
Shackle
EPA Registration No. 524-330
Polado Plant Growth Regulator
EPA Registration No. 524-332
Shackle C
EPA Registration No. 524-339
Rodeo Herbicide
EPA Registration No. 524-343
Landmaster Herbicide
EPA Registration No. 524-351
Your Letter of October 14, 1985

We have your letter of October 14, 1985 transmitting product chemistry data in support of the subject registrations. This information has been added to the files. The accession number assigned these data is 260020.

Sincerely yours,

Robert J. Taylor VKW
Product Manager (25)
Fungicide-Herbicide Branch
Registration Division (TS-767C)

Monsanto

Monsanto Company
1101 17th Street, N.W.
Washington, D.C. 20036
Phone: (202) 452-8880

October 14, 1985

Director
Registration Division (TS767C)
Office of Pesticide Programs
U. S. Environmental Protection Agency
1921 Jefferson Davis Highway
Crystal Mall #2, Room 716D
Arlington, Virginia 22202

Attention: Mr. Robert J. Taylor
Product Manager (25)

Subject: Roundup® Herbicide
EPA Reg. Nos. 524-308,
524-330, 524-332, 524-339,
524-343, 524-351, 524-370
Submission of Additional
Glyphosate Product Chemistry
Data.

Dear Sir:

At this time, Monsanto Company submits the "Selected Product Chemistry Data to Support the Continued Registration of Glyphosate (N-Phosphonomethylglycine)" study (R.D. No. 640) as additional Product Chemistry data to support Roundup®, Shackle®, Shackle® C, Landmaster®, Roundup® L & G, Rodeo®, and Polado® Plant Growth Regulator herbicides' registrations.

Please inform me of the accession number assigned to this submission. If you have any questions about this submission, please contact Lyle Gingerich or me.

Sincerely,

Tom Armstrong

Thomas F. Armstrong
Registration Manager

/pt
Enclosures

cc: L. L. Gingerich

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

OCT 16 1985

Monsanto Company
1101 17th Street NW.
Washington, DC 20036

yellow copy

Attention: Thomas F. Armstrong

Gentlemen:

Subject: Roundup Herbicide (Recut Slides for
Chronic Mouse Study)
EPA Registration No. 524-308
Shackle
EPA Registration No. 524-330
Polardo Plant Growth Regulator
EPA Registration No. 524-332
Shackle
EPA Registration No. 524-339 ✓
Rodeo Herbicide
EPA Registration No. 524-343
Landmaster Herbicide
EPA Registration No. 524-351
Your Letter of October 7, 1985

We have your letter of October 7, 1985, transmitting an addendum to the chronic mouse study. Further action will await completion of scientific review and evaluation.

The Accession Number assigned these data is 259621.

Sincerely yours,

URW

Robert J. Taylor
Product Manager (25)
Fungicide-Herbicide Branch
Registration Division (TS-767C)

Monsanto

Monsanto Company
1101 17th Street, N.W.
Washington, D.C. 20036
Phone: (202) 452-8880
October 7, 1985

Director
Registration Division (TS767C)
Office of Pesticide Programs
U. S. Environmental Protection Agency
1921 Jefferson Davis Highway
Crystal Mall #2, Room 716D
Arlington, Virginia 22202

Attention: Mr. Robert J. Taylor
Product Manager (25)

Subject: Roundup® Herbicide
EPA Reg. Nos.
524-308, 524-330, 524-332,
524-339, 524-343, 524-351
Addendum to Chronic Mouse
Study with Glyphosate.

Dear Sir:

Due to the Agency's continuing concern relative to the incidence of kidney tumors in the chronic mouse study with glyphosate, the Agency requested (in their July 29, 1985 letter) Monsanto to have the glyphosate chronic mouse study kidneys systematically and uniformly recut to obtain further information on the presence or absence of these kidney tumors.

To comply with the Agency's July 29, 1985 request, Monsanto is now submitting a "Pathology Report on Additional Kidney Sections Addendum to Final Report dated July 21, 1983" report (RD No. 635). Please inform us of the petition and accession numbers assigned to this submission.

In summary, the EPA requested review of the recut kidney sections revealed the following:

> Confirmation of diagnosis for the original renal tubular adenomas was made, including concurrence with Dr. Marvin Kuschner on the presence of a lesion in the control group which represented a developing tumor. No new tumors were found in any of the control or treated groups. Thus, the

overall incidence of renal tubular adenomas in control, low, mid, and high dose groups was 1/49, 0/49, 1/50, 3/50, respectively. Statistical analysis of this data reveals no statistically significant difference between any of the treated and control groups, and no statistically significant trend.

In conclusion, a thorough evaluation of the kidneys of male mice exposed to dietary levels of glyphosate of 1,000, 5,000, and 30,000 ppm for 24 months revealed no evidence of chemically-induced nephrotoxicity. The renal tumors observed were considered to be incidental and not toxicologically significant.

Based on this information and the previously submitted information which demonstrated that glyphosate did not show a treatment-related oncogenic effect in this chronic mouse study, Monsanto is hopeful that the Agency will reach the same conclusion. In addition, we request that the review of all pending glyphosate petitions now be completed.

Sincerely,

Thomas Armstrong

Thomas F. Armstrong
Registration Manager

/pt
Enclosures

cc: L. L. Gingerich

Monsanto

Monsanto Company
1101 17th Street, N.W.
Washington, D.C. 20036
Phone: (202) 452-8880

February 12, 1985

Director
Registration Division (TS767C)
Office of Pesticide Programs
U. S. Environmental Protection Agency
1921 Jefferson Davis Highway
Crystal Mall #2, Room 716D
Arlington, Virginia 22202

Attention: Mr. Robert J. Taylor
Product Manager (25)

Subject: Shackle® C Herbicide
EPA Reg. No. 524-339
Update Storage and
Disposal Statements
54 Gallon Container Label

Dear Sir:

PR Notice 83-3 requires that the labels of pesticides include updated Storage and Disposal statements. Monsanto requested amendments in the Storage and Disposal language as it had been set forth in PR Notice 83-3. The requested amendments were approved by Douglas D. Campt on August 24, 1984.

To comply with PR Notice 83-3, attached for your files are five (5) copies of the Shackle C 54 Gallon container label which contains the approved Storage and Disposal statements.

If you have any questions, please contact Lyle Gingerich or myself.

Sincerely,

Tom Armstrong

Thomas F. Armstrong
Registration Manager

/pt
Enclosures

cc: L. L. Gingerich

LIMIT OF WARRANTY AND LIABI

This company warrants that this product conforms to the chemical description on this label. NO OTHER EXPRESS OR IMPLIED WARRANTY OF FITNESS FOR PARTICULAR PURPOSE OR MERCHANTABILITY IS MADE. This warranty is also subject to the conditions and limitations stated herein.

Buyer and all users shall promptly notify this company of any claims whether based in contract, negligence, strict liability, other tort or otherwise.

Buyer and all users are responsible for all loss or damage from use or handling which results from conditions beyond the control of this company, including but not limited to uses or applications in any manner not explicitly set forth in this label or application to or contact with desirable vegetation.

THE EXCLUSIVE REMEDY OF THE USER OR BUYER, AND THE LIMIT OF THE LIABILITY OF THIS COMPANY OR ANY OTHER SELLER FOR ANY AND ALL LOSSES, INJURIES OR DAMAGES RESULTING FROM THE USE OR HANDLING OF THIS PRODUCT (INCLUDING CLAIMS BASED IN CONTRACT, NEGLIGENCE, STRICT LIABILITY, OTHER TORT OR OTHERWISE) SHALL BE THE PURCHASE PRICE PAID BY THE USER OR BUYER FOR THE QUANTITY OF THIS PRODUCT INVOLVED, OR, AT THE ELECTION OF THIS COMPANY OR ANY OTHER SELLER, THE REPLACEMENT OF SUCH QUANTITY OR, IF NOT ACQUIRED BY PURCHASE, REPLACEMENT OF SUCH QUANTITY. IN NO EVENT SHALL THIS COMPANY OR ANY OTHER SELLER BE LIABLE FOR ANY INCIDENTAL OR CONSEQUENTIAL DAMAGES.

The buyer and all users are deemed to have accepted the terms of this LIMIT OF WARRANTY AND LIABILITY which may not be varied by any verbal or written agreement.

U.S. Pat. No. 3,799,758 and U.S. Pat. No. 4,405,531 covers use. Other patents are pending.

MONSANTO COMPANY
AGRICULTURAL PRODUCTS
ST. LOUIS, MISSOURI 63167 U.S.A.

MAP-2233.03/53L

PRECAUTIO RY STATEMENTS

Hazard to Humans and Domestic Animals

Keep out of reach of children.

WARNING!

CAUSES EYE IRRITATION.

HARMFUL IF SWALLOWED.

Do not get in eyes, on skin or on clothing.

FIRST AID: In case of contact, immediately flush eyes with plenty of water for at least 15 minutes. Call a physician. Flush skin with water. Wash clothing before reuse.

Environmental Hazards

Keep out of lakes, streams and ponds. Do not contaminate water by disposal of waste or cleaning of equipment.

Physical or Chemical Hazards

Solutions of this product should be mixed and stored only in stainless steel, aluminum, fiberglass, plastic and plastic-lined steel containers.

DO NOT MIX OR STORE THIS PRODUCT OR SOLUTIONS OF THIS PRODUCT IN GALVANIZED STEEL OR UNLINED STEEL (EXCEPT STAINLESS STEEL) CONTAINERS OR SPRAY TANKS.

This product or solutions of this product react with such containers and tanks to produce hydrogen gas which may form a highly combustible gas mixture. This gas mixture could flash or explode, causing serious personal injury, if ignited by open flame, spark, welder's torch, lighted cigarette, or other ignition source.

Storage and Disposal

Do not contaminate water, food, or feed by storage or disposal.

Wastes resulting from the use of this product that cannot be used or chemically reprocessed should be disposed of in a landfill approved for pesticide disposal or buried on site in a safe place away from water supplies. All disposal should be in accordance with applicable Federal, state or local procedures.

Emptied container retains vapor and product residue. Observe all labeled safeguards until container is cleaned, reconditioned or destroyed. DO NOT CUT OR WELD ON OR NEAR THIS CONTAINER.

Triple rinse emptied container. Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or by other procedures approved by state and local authorities.

CONCENTRATE

SHACKLE® C

HERBICIDE BY Monsanto

For formulation of products (not to exceed 10% active ingredient) for weed and grass control in home lawns and gardens.

It is a violation of Federal Law to use this product in any manner inconsistent with its labeling.

Read the entire label before using this product.

Read "LIMIT OF WARRANTY AND LIABILITY" before buying or using. If terms are not acceptable, return at once unopened.

Keep out of reach of children.

WARNING! Read precautions on side panel.

In case of an emergency involving this product, Call Collect, day or night, (314) 694-4000.

ACTIVE INGREDIENT:	
*Isopropylamine salt of glyphosate	41.0%
INERT INGREDIENTS:	59.0%
	100.0%

*Contains 480 grams per liter or 4 pounds of the active ingredient isopropylamine salt of N-(phosphonomethyl) glycine per U.S. gallon.

Equivalent to 356 grams per liter or 3 pounds per U.S. gallon of the acid, glyphosate.

EPA Reg. No. 524-339

EPA Est. 524-LA-1

NOT REVIEWED
In Accordance with PR Notice 82-2.
Based on Draft Labeling Dated

NET 54 U.S. GAL.

5-10-82

EBW-68

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C 20460

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

JAN 23 1985

yellow copy

Monsanto Company
1101 17th Street, NW
Washington, DC 20036

Attention: Tom Armstrong

Gentlemen:

Subject: Roundup Herbicide (Cattle Palatability Study)
EPA Registration No. 524-308
Shackle Herbicide
EPA Registration No. 524-330
Shackle C Herbicide
EPA Registration No. 524-339
Polado Herbicide
EPA Registration No. 524-332
Rodeo Herbicide
EPA Registration No. 524-343
Your Letter of August 30, 1984

The scientific review and evaluation of the study submitted have been completed. The following are our comments and/or conclusions:

1. The feeding of concentrate diet did not result in any significant differences in feed consumption, milk production or animal health or behavior.

2. The Milk and Meat Residue Study with glyposate and aminomethylphosphonic acid is now considered valid.

Sincerely yours,

Robert J. Taylor
Product Manager (25)
Fungicide-Herbicide Branch
Registration Division (TS-767C)

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

JAN 4 1985

MEMORANDUM

SUBJECT: RCB Review of IBT Validation Report. Milk and Meat Residue Study with Glyphosate and Aminomethylphosphonic Acid.IBT #651-3775. Addendum of 9/10/84.

FROM: Edward Zager, Section Head,
Special Registration Section 2
Residue Chemistry Branch,
Hazard Evaluation Division (TS-769)

Edward Zager

TRU: Charles L. Trichilo, Ph.D., Chief
Residue Chemistry Branch
Hazard Evaluation Division (TS-769)

CLT

To: Vicki Walters
PM-25, Registration Division (TS-767)

RCB classified IBT study #651-3775 as invalid due to the lack of feed consumption data. We expressed particular concern that the addition of the glyphosate:aminomethylphosphonic acid mixture to the diet rendered it unpalatable thus causing the amount of test material consumed by the cows to be significantly less than stated in the protocol.

To validate the study, Monsanto has now submitted the results of a study in which 3 lactating dairy cattle received concentrate diets fortified with 400 ppm glyphosate and aminomethylphosphonic acid in a 3:1 ratio. Three controls were administered non-fortified diets. The feeding of concentrate diets did not result in any significant differences in feed consumption, milk production or animal health or behavior.

RCB now considers the Milk and Meat Residue Study with Glyphosate and Aminomethylphosphonic Acid to be valid.

cc:R.F., Circu, Reviewer, S.F. (Glyphosate)
TS-769:E. Zager:Revised by:wh:1/4/84

JAN 28 1985

Monsanto Company
1101 17th Street NW.
Washington, DC 20036

Attention: Tom F. Armstrong

Gentlemen:

Subject: Shackle Herbicide (Update Storage and Disposal Statements)
EPA Registration No. 524-339
Your Letter Dated December 5, 1984

The labeling referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act, as amended, is acceptable. A stamped copy is enclosed for your records.

Sincerely yours,

Robert J. Taylor
Product Manager (25)
Fungicide-Herbicide Branch
Registration Division (TS-767C)

Enclosure

RD/FHB:JOB:89300:R.Taylor:RD-25:eg:Kendrick:898-1270:1/22/85:Del.1/27/85

CONCURRENCES

SYMBOL ▶	TS-767C							
SURNAME ▶	VKWalker							
DATE ▶	1/28/85							

EPA Form 1320-1 (4-81)

OFFICIAL FILE COPY

LIMIT OF WARRANTY AND LIABILITY

This company warrants that this product conforms to the chemical description on this label. NO OTHER EXPRESS OR IMPLIED WARRANTY OF FITNESS FOR PARTICULAR PURPOSE OR MERCHANTABILITY IS MADE. This warranty is also subject to the conditions and limitations stated herein.

Buyer and all users shall promptly notify this company of any claims whether based in contract, negligence, strict liability, other tort or otherwise.

Buyer and all users are responsible for all loss or damage from use or handling which results from conditions beyond the control of this company, including but not limited to uses or applications in any manner not explicitly set forth in this label or application to or contact with desirable vegetation.

THE EXCLUSIVE REMEDY OF THE USER OR BUYER, AND THE LIMIT OF THE LIABILITY OF THIS COMPANY OR ANY OTHER SELLER FOR ANY AND ALL LOSSES, INJURIES OR DAMAGES RESULTING FROM THE USE OR HANDLING OF THIS PRODUCT (INCLUDING CLAIMS BASED IN CONTRACT, NEGLIGENCE, STRICT LIABILITY, OTHER TORT OR OTHERWISE) SHALL BE THE PURCHASE PRICE PAID BY THE USER OR BUYER FOR THE QUANTITY OF THIS PRODUCT INVOLVED, OR, AT THE ELECTION OF THIS COMPANY OR ANY OTHER SELLER, THE REPLACEMENT OF SUCH QUANTITY OR, IF NOT ACQUIRED BY PURCHASE, REPLACEMENT OF SUCH QUANTITY. IN NO EVENT SHALL THIS COMPANY OR ANY OTHER SELLER BE LIABLE FOR ANY INCIDENTAL OR CONSEQUENTIAL DAMAGES.

The buyer and all users are deemed to have accepted the terms of this LIMIT OF WARRANTY AND LIABILITY which may not be varied by any verbal or written agreement.

U.S. Pat. No. 2,799,758 covers use. Other patents are pending.

MONSANTO COMPANY
AGRICULTURAL PRODUCTS
ST. LOUIS, MISSOURI 63167 U.S.A.

MAP-2233.02/53F

PRECAUTIONARY STATEMENTS

Hazard to Humans and Domestic Animals

Keep out of reach of children.

WARNING!

CAUSES EYE IRRITATION.

HARMFUL IF SWALLOWED.

Do not get in eyes, on skin or on clothing.

FIRST AID: In case of contact, immediately flush eyes with plenty of water for at least 15 minutes. Call a physician. Flush skin with water. Wash clothing before reuse.

Environmental Hazards

Keep out of lakes, streams and ponds. Do not contaminate water by disposal of waste or cleaning of equipment.

Physical or Chemical Hazards

Solutions of this product should be mixed and stored only in stainless steel, aluminum, fiberglass, plastic and plastic-lined steel containers.

DO NOT MIX OR STORE THIS PRODUCT OR SOLUTIONS OF THIS PRODUCT IN GALVANIZED STEEL OR UNLINED STEEL (EXCEPT STAINLESS STEEL) CONTAINERS OR SPRAY TANKS.

This product or solutions of this product react with such containers and tanks to produce hydrogen gas which may form a highly combustible gas mixture. This gas mixture could flash or explode, causing serious personal injury, if ignited by open flame, spark, welder's torch, lighted cigarette, or other ignition source.

Storage and Disposal

Do not contaminate water, food, or feed by storage or disposal.

Wastes resulting from the use of this product that cannot be used or chemically reprocessed should be disposed of in a landfill approved for pesticide disposal or buried on site in a safe place away from water supplies. All disposal should be in accordance with applicable Federal, state or local procedures.

Emptied container retains vapor and product residue. Observe all labeled safeguards until container is cleaned, reconditioned or destroyed. DO NOT CUT OR WELD ON OR NEAR THIS CONTAINER.

Triple rinse emptied bulk containers. Then offer for recycling or reconditioning, or dispose of in a manner approved by state and local authorities.

CONCENTRATE

SHACKLE® C

306

HERBICIDE BY Monsanto

For formulation of products (not to exceed 10% active ingredient) for weed and grass control in home lawns and gardens.

It is a violation of Federal Law to use this product in any manner inconsistent with its labeling.

Read the entire label.

Read "LIMIT OF WARRANTY AND LIABILITY" before buying or using. If terms are not acceptable, return at once unopened.

Keep out of reach of children.

WARNING! Read precautions on side panel.

ACCEPTED
JAN 2 8 1985
Under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, for the pesticide registered under EPA Reg. No. 524-339

ACTIVE INGREDIENT:	
*Isopropylamine salt of glyphosate	41.0%
INERT INGREDIENTS:	59.0%
	100.0%

*Contains 480 grams per liter or 4 pounds of the active ingredient isopropylamine salt of N-(phosphonomethyl) glycine per U.S. gallon.

Equivalent to 356 grams per liter or 3 pounds per U.S. gallon of the acid, glyphosate.

EPA Reg. No. 524-339

EPA Est. 524-NC-1

In case of an emergency involving this product, Call Collect, day or night, (314) 694-4000.

NET U.S. GAL.

SUBMISSION REVIEW RECORD G

1. REGISTRATION NUMBER	CYCLE	2. DATE RECEIVED (MO / DAY / YR)
524 - 333		

3. 3CID PUBLICATION NECESSARY	4. PETITION NO.	5. RECEIVED PM TEAM (MO / DAY / YR)
☐ YES ☐ NO		

6. METHOD OF SUPPORT	7. PRODUCT MANAGER	NO.	8. PROJECTED RETURN (MO / DAY / YR)
☐ 2A ☐ 2B ☐ 2C			

9. DATE PULLED	10. DATE PUBLISHED	11. ACTION TYPE	CODE	12. OUTGOING DATE (MO / DAY / YR)
1/17/85		Update St² Disposal on R/4 5 container Label 300		

REV. SEQ.	REVIEW TYPE CODE	REVIEW TYPE	REVIEWER CODE (Initials)	SIGNATURE OF REVIEWER	COMMENT CODE	DATE REVIEW COMPLETED (MO / DAY / YR)
	A	REVIEWABILITY TEAM				
	B	PRODUCT MANAGER TEAM EFFICACY REVIEW				
	C	PRODUCT MANAGER TEAM HUMAN SAFETY REVIEW				
	D	PRODUCT MANAGER TEAM ENVIRONMENTAL SAFETY REVIEW				
	E	PRODUCT MANAGER TEAM RESUBMISSION REVIEW				
	F	PRODUCT MANAGER		VKW	NAC	01 17 85
	G	INTERAGENCY REFERRAL				
	H	COST-BENEFIT REVIEW				
	I	PUBLIC COMMENTS REVIEW				
	J	EEE BRANCH INSECTICIDE EFFICACY				
	K	EEE BRANCH HERBICIDE EFFICACY				
	L	EEE BRANCH FUNGICIDE EFFICACY				
	M	EEE BRANCH RODENTICIDE EFFICACY				
	N	EEE BRANCH DISINFECTANT EFFICACY				
	O	CHEMISTRY BRANCH RESIDUE CHEMISTRY				
	P	EEE BRANCH ENVIRON - MENTAL CHEMISTRY				
	Q	TOXICOLOGY BRANCH HUMAN SAFETY				
	R	EEE BRANCH ENVIRON- MENTAL SAFETY				
	S					
	T					

PRODUCT MANAGER SIGNATURE	TYPE OF RESPONSE	CODE

EPA Form 8570-13 (3-75)

Monsanto

Monsanto Company
1101 17th Street, N.W.
Washington, D.C. 20036
Phone: (202) 452-8860

December 5, 1984

Director
Registration Division (TS767C)
Office of Pesticide Programs
U. S. Environmental Protection Agency
1921 Jefferson Davis Highway
Crystal Mall #2, Room 716D
Arlington, Virginia 22202

Attention: Mr. Robert J. Taylor
Product Manager (25)

Subject: Shackle® C Herbicide
EPA Reg. No. 524-339
Update Storage and
Disposal Statements
Container Label

Dear Sir:

PR Notice 83-3 requires that the labels of pesticides include updated Storage and Disposal statements. Monsanto requested amendments in the Storage and Disposal language as it had been set forth in PR Notice 83-3. The requested amendments were approved by Douglas D. Campt on August 24, 1984.

To comply with PR Notice 83-3, attached for your files are five (5) copies of the Shackle C container label which contains the approved Storage and Disposal statements.

If you have any questions, please contact Lyle Gingerich or myself.

Sincerely,

Tom Armstrong

Thomas F. Armstrong
Registration Manager

/pt
Enclosures

cc: L. L. Gingericb

43-11-21

34 043

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

NOV 16 1984

Monsanto Company
1101 17th Street, NW
Washington, DC 20036

Attention: Glynadee Edwards

Gentlemen:

Subject: Shackle C Herbicide
EPA Registration No. 524-339
Your Letter of February 23, 1984
Re: Acute Inhalation and Dermal Sensitization Studies

We have completed a review of your request for a waiver of the above data requirements. Based on information submitted in your letter of February 23, 1984, the Acute Inhalation and Dermal Sensitization Studies are waived.

No additional precautionary statements are required, as this time.

Sincerely yours,

Robert J. Taylor
Product Manager (25)
Fungicide-Herbicide Branch
Registration Division (TS-767C)

RD:45058:Taylor:RD-19:sah:11/14/84:Kenderick & Co., 898-1270:Del.11/27/84

CONCURRENCES

SYMBOL ▶	TS-767C							
SURNAME ▶	J. Miller							
DATE ▶	11-16-84							

EPA Form 1320-1 (4-81)

OFFICIAL FILE COPY

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

Date: October 22, 1984

Subject: EPA Registration Number 524-339
Shackle C Herbicide

From: Deloris F. Graham DFG 10/25/84
FHB/TSS E 10/31/84

To: Robert Taylor
Product Manager (25)

Applicant: Monsanto Agricultural Products Co.
800 N. Lindbergh Boulevard
St. Louis, MO 63166

Active Ingredient:
Isopropylamine salt of Glyphosate 41.0%
Inert Ingredients 59.0%

Background: Submitted information in a letter dated February 23, 1984, to the Agency to support waiver of Acute Inhalation and Dermal Sensitization Studies.

Recommendation:
(1) Based on information submitted in the letter dated February 23, 1984, the Acute Inhalation Study and Dermal Sensitization studies can be waived.

Monsanto

Monsanto Company
1101 17th Street, N. W.
Washington, D. C. 20036
Phone: (202) 452-8860
February 23, 1984

Director
Registration Division (TS767C)
Office of Pesticide Programs
U. S. Environmental Protection Agency
1921 Jefferson Davis Highway
Crystal Mall #2, Room 716D
Arlington, Virginia 22202

Attention: Mr. Robert J. Taylor
Product Manager (25)

Subject: Shackle® C Herbicide
EPA Reg. No. 524-339
Acute Inhalation and
Dermal Sensitization Studies

Dear Sir:

Several of our Shackle® C formulators have contacted us concerning the denial of their registrations because Monsanto did not submit the following studies on the 10% solution:

158.135 (81-3) Acute Inhalation LC_{50}
158.135 (81-6) Dermal Sensitization

We submitted an Acute Inhalation LC_{50} Study for Roundup® Herbicide in March 1982 (EPA Accession Number 247188). The study was accepted by the Agency as core minimum. The results indicated that Roundup® Herbicide possesses a relatively low acute inhalation hazard (4-hr LC_{50} = 3.18 mg/ℓ). A dilution of Roundup® Herbicide with water would not result in an acute inhalation hazard. We feel an acute inhalation study for the 10% solution is not required.

On January 3, 1984, Monsanto submitted a Dermal Sensitization Study in Guinea Pigs with Roundup® Formulation (RD 515, Part 1). Results of the Range-finding Study, a 100% concentration was found to be non-irritating and was selected as the concentration to use. A 10% solution was also used in the range-finding study. Since the use of the formulator's products will not result in repeated human skin contact, we feel a study for the 10% solution is not required.

We feel we have submitted the required studies and request the Agency to proceed with registration of the formulators' products.

Should you have questions, please contact Monsanto.

Sincerely,

Glynadee Edwards

Glynadee Edwards
Registration Manager

/pt

cc: L. L. Gingerich

REGISTRATION DIVISION DATA REVIEW RECORD

Confidential Business Information – Does Not Contain National Security Information (E.O. 12065)

1. CHEMICAL NAME: Isopropylamine Salt of Glyphosate

2. IDENTIFYING NUMBER	3. ACTION CODE	4. ACCESSION NUMBER	TO BE COMPLETED BY PM
524-339	305		5. RECORD NUMBER: 122,541
			6. REFERENCE NUMBER: 4
			7. DATE RECEIVED (EPA): 3/1/84
			8. STATUTORY DUE DATE:
			9. PRODUCT MANAGER (PM): TAYLOR/J. Miller
			10. PM TEAM NUMBER: 25

14. CHECK IF APPLICABLE

- ☐ Public Health/Quarantine
- ☐ Minor Use
- ☐ Substitute Chemical
- ☐ Part of IPM
- ☐ Seasonal Concern
- ☐ Review Requires Less Than 4 Hours

TO BE COMPLETED BY PCB

11. DATE SENT TO HED/TSS:

12. PRIORITY NUMBER:

13. PROJECTED RETURN DATE:

15. INSTRUCTIONS TO REVIEWER

A. HED
- ☐ Total Assessment - 3(c)(5)
- ☐ Incremental Risk Assessment - 3(c)(7) and/or E.L. Johnson memo of May 12, 1977.

B. SPRD (Send Copy of Form to SPRD PM)
- ☐ Chemical Undergoing Active RPAR Review
- ☐ Chemical Undergoing Active Registration Standards Review

C. ☐ BFSD

D. ☒ TSS/RD

E. ☐ Other

F. INSTRUCTIONS: Precautionary labeling - Review remarks concerning Acute Inhalation & Dermal Sensitization Studies

16. RELATED ACTIONS:

17. 3(c)(1)(D)
- ☐ Use Any or All Available Information
- ☐ Use Only Attached Data
- ☐ Use Only the Attached Data for Formulation and Any or All Available Information on the Technical or Manufacturing Chemical.

18. REVIEWS SENT TO
- ☐ TB
- ☐ EEB
- ☐ EF
- ☒ PL
- ☐ RCB
- ☐ EFB
- ☐ CH
- ☐ BFSD

19.	To	TYPE OF REVIEW	NUMBER OF ACTIONS: Registration	Petition	EUP	SLN	Sec. 18	Inert	MNR. USE	Other
HED		TOXICOLOGY								
HED		ECOLOGICAL EFFECTS								
HED		RESIDUE CHEMISTRY								
HED		ENVIRONMENTAL DATE								
RD/TSS		CHEMISTRY								
RD/TSS		EFFICACY								
RD/TSS	X	PRECAUTIONARY LABELING	1							
BFSD		ECONOMIC ANALYSIS								

20. ☐ Label Submitted with Application Attached

21. ☐ Confidential Statement of Formula

22. ☐ Representative Labels Showing Accepted Uses Attached

23. Date Returned to RD (to be completed by HED)

24. Include an Original and 4 (four) Copies of This Completed Form for Each Branch Checked for Review.

EPA Form 8570-13 (Rev. 11-81) PREVIOUS EDITIONS ARE OBSOLETE.

Monsanto

Monsanto Company
1101 17th Street, N.W.
Washington, D.C. 20036
Phone: (202) 452-8880

August 29, 1984

Director
Registration Division (TS767C)
Office of Pesticide Programs
U.S. Environmental Protection Agency
1921 Jefferson Davis Highway
Crystal Mall #2 Room 716D
Arlington, Virginia 22202

Attention: Mr. Robert J. Taylor
Product Manager (25)

Study routed to TB for review.
Duplicate sent to clear formulations. Board on 10/25/84 review
Dermal Sens not needed for 10% so will wait TB review
Pd not route to Diane's

Shackle® C. Herbicide
EPA Reg. No. 524-339
Acute Dermal Sensitization Data

Dear Sir:

On September 14, 1983 Monsanto submitted four acute toxicity and irritation studies conducted with a water dilution of Shackle® C to a concentration of 10% AI (isopropylamine salt of glyphosate).

These studies were intended to support (by specific authorization only) future registrations that contain 10% by weight isopropylamine salt of glyphosate and that are water dilutions of Shackle® C.

The Agency completed its review of these studies and indicated in its February 22, 1984 letter (attached) that acute inhalation and dermal sensitization studies should be submitted.

We are submitting at this time a Acute Dermal Sensitization Study with Roundup® Herbicide, BD 83-007, compiled in one volume designated RD #551, August 29, 1984.

Shackle® C. herbicide (concentrate) has exactly the same composition as Roundup® herbicide. Hence, the dermal sensitization study with Roundup® herbicide, submitted herewith, should be applicable in support of the registration of a water dilution of Shackle® C to 10% AI. The results of the Roundup dermal sensitization study demonstrate that Roundup did not produce sensitization in guinea pigs. Simple dilution of this product with water should not change these results.

With respect to the question on the acute inhalation study, we believe the acute inhalation study with Roundup, accession number 247188, accepted by the Agency as core-minimum, should also suffice in support of the Shackle® C (10% AI) formulation. The four hour LC_{50} for Roundup was determined to be 3.18 mg/l.

In summary, we believe the dermal sensitization study submitted herewith and the previously submitted and accepted acute inhalation study satisfy the two data gaps cited in your February 22, 1984 letter.

We request your concurrence with this position. We also request that this data serve to support duly authorized end-use formulators requests for registration of products consisting of Shackle® C diluted to 10% AI.

Should there be any questions, please contact our Washington office.

Sincerely,

R. W. Street

R. W. Street
Manager, Product Health and
Safety Information

RWS:yrs

Attachments

cc: L. L. Gingerich

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

22 FEB 1984

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

Monsanto Company
1101 17th Street, NW.
Washington, DC 20036

Attention: Mr. Tom Armstrong

Gentlemen:

Subject: Shackle C Herbicide (Acute Toxicity Tests)
EPA Registration No. 524-339
Your Letter of September 14, 1983

The scientific review and evaluation of the acute studies submitted have been completed. The following are our comments and/or conclusions.

Review of Data:

1. The LD_{50} is greater than 5000 mg/kg.
2. This study is classified as core guideline data.
3. The toxicity category is IV - Caution.

Acute Dermal Toxicity Study

1. The LD_{50} is greater than 5000 mg/kg
2. This study is classified as core guideline data
3. The toxicity category is IV - Caution.

Primary Skin Irritation Study

1. No irritation present at 24 or 72 hours after treatment. Primary irritation score was zero.
2. This study is classified as core guideline data
3. The toxicity category is IV - Caution.

Eye Irritation Study

1. All irritation had cleared by day 7.

2. This study is classified as core guideline data

3. The toxicity category is III - Caution.

Conclusions:

1. The available data support the conditional registration of the product tested.

2. To meet the requirements under conditional registration an acute inhalation and dermal sensitization should be submitted.

3. A final decision on precautionary labeling will await submission of requested data.

Sincerely yours,

Robert J. Taylor
Product Manager (25)
Fungicide-Herbicide Branch
Registration Division (TS-767C)

DATA SUBMISSION LISTING

Product Name
Shackle® C Herbicides

EPA Reg. No./File Symbol
524-339

Page 1 **of** 1

Applicant's Name and Address
Monsanto Company
1101 17th Street N.W.
Washington, D.C. 20036

To accompany application for registration dated
None

319

NAME OF STUDY	SOURCE OF STUDY: APPLICANT CONDUCTED STUDY	OBTAINED FROM EPA	OBTAINED FROM ANOTHER FIRM OR SOURCE GIVE NAME AND ADDRESS	OBTAINED FROM PUBLIC LITERATURE GIVE REFERENCE	OTHER EXPLAIN	ACCESSION NUMBER EPA USE ONLY
A Dermal Sensitization Study in Guinea Pigs with Roundup® Formulation	X					
IF YOU CHECKED THIS COLUMN → DO YOU WISH YOUR NAME PLACED ON THE DATA SUBMITTERS LIST? ☒ YES. ☐ NO		●		●		

22 FEB 1984

Monsanto Company
1101 17th Street, NW.
Washington, DC 20036

Attention: Mr. Tom Armstrong

Gentlemen:

Subject: Shackle C Herbicide (Acute Toxicity Tests)
EPA Registration No. 524-339
Your Letter of September 14, 1983

The scientific review and evaluation of the acute studies submitted have been completed. The following are our comments and/or conclusions.

Review of Data:

1. The LD_{50} is greater than 5000 mg/kg.

2. This study is classified as core guideline data.

3. The toxicity category is IV - Caution.

Acute Dermal Toxicity Study

1. The LD_{50} is greater than 5000 mg/kg

2. This study is classified as core guideline data

3. The toxicity category is IV - Caution.

Primary Skin Irritation Study

1. No irritation present at 24 or 72 hours after treatment. Primary irritation score was zero.

2. This study is classified as core guideline data

3. The toxicity category is IV - Caution.

CONCURRENCES								
SYMBOL ▶	TS-767C							
SURNAME ▶	V.K.Walker							
DATE ▶	2/22/84							

EPA Form 1320-1 (4-81) OFFICIAL FILE COPY

Eye Irritation Study

1. All irritation had cleared by day 7.

2. This study is classified as core guideline data

3. The toxicity category is III - Caution.

Conclusions:

1. The available data support the conditional registration of the product tested.

2. To meet the requirements under conditional registration an acute inhalation and dermal sensitization should be submitted.

3. A final decision on precautionary labeling will await submission of requested data.

Sincerely yours,

Robert J. Taylor
Product Manager (25)
Fungicide-Herbicide Branch
Registration Division (TS-767C)

RD-FHB:DCR-04364:Taylor:pac:Raven:557-2226:RD-03A:2/21/84:3/3/84

SUBMISSION REVIEW RECORD G	1. REGISTRATION NUMBER	CYCLE	2. DATE RECEIVED
	524 - 3319		MO 10 DAY 03 YR 83

3. ECIC PUBLICATION NECESSARY	4. PETITION NO.	5. RECEIVED PM TEAM
☐ YES ☐ NO		MO DAY YR

6. METHOD OF SUPPORT	7. PRODUCT MANAGER	NO.	8. PROJECTED RETURN
☐ 2A ☐ 2B ☐ 2C			MO 11 DAY 14 YR 83

9. DATE PULLED	10. DATE PUBLISHED	11. ACTION TYPE	CODE	12. OUTGOING DATE
10/14/83		Quote To Test RJ#3 400		MO 10 DAY 14 YR 83

REV. SEQ.	REVIEW TYPE CODE	REVIEW TYPE	REVIEWER CODE (Initials)	SIGNATURE OF REVIEWER	COMMENT CODE	DATE REVIEW COMPLETED MO	DAY	YR
	A	REVIEWABILITY TEAM						
	B	PRODUCT MANAGER TEAM EFFICACY REVIEW						
	C	PRODUCT MANAGER TEAM HUMAN SAFETY REVIEW						
	D	PRODUCT MANAGER TEAM ENVIRONMENTAL SAFETY REVIEW						
	E	PRODUCT MANAGER TEAM RESUBMISSION REVIEW						
	F	PRODUCT MANAGER		VKW.	comment	02	17	84
	G	INTERAGENCY REFERRAL						
	H	COST-BENEFIT REVIEW						
	I	PUBLIC COMMENTS REVIEW						
	J	EEB BRANCH INSECTICIDE EFFICACY						
	K	EEB BRANCH HERBICIDE EFFICACY						
	L	EEB BRANCH FUNGICIDE EFFICACY						
	M	EEB BRANCH RODENTICIDE EFFICACY						
	N	EEB BRANCH DISINFECTANT EFFICACY						
	O	CHEMISTRY BRANCH RESIDUE CHEMISTRY						
	P	EEB BRANCH ENVIRONMENTAL CHEMISTRY						
	O	TOXICOLOGY BRANCH HUMAN SAFETY						
	R	EEB BRANCH ENVIRONMENTAL SAFETY						
✓	S	TSS/PL	DFH	Delores F. Graham	RL	02	06	84
	T							

PRODUCT MANAGER SIGNATURE	TYPE OF RESPONSE	CODE

EPA Form 8570-13 (3-75)

Date: February 6, 1984

Subject: EPA Registration Number: 524-339
Shackle C Herbicide

From: Delores J. Graham
FHB/SRS E 2/8/84

To: Robert Taylor
Product Manager (25)

Applicant: Monsanto Agricultural Products Co.
800 N. Lindbergh Boulevard
St. Louis, Missouri 63166

Active Ingredient:
Isopropylamine salt of Glyphosate 41.0%
Inert Ingredients 59.0%

Background: Submitted Acute Oral, Acute Dermal, Eye Irritation and Primary Dermal Irritation Studies as miscellaneous data, not requested by Agency. However the studies were conducted using Shackle C Herbicide diluted to 10% isopropylamine salt of glyphosate with water prior to shipment to the test facility. Studies conducted. Studies conducted by Monsanto Environmental Health Laboratory. Data under accession number 251942. Method of support not indicated.

Recommendation
(1) FHB/SRS finds these data acceptable to support conditional registration for the

product tested.

(2) To meet requirements under conditional registration an Acute Inhalation and Dermal Sensitization study would have to be submitted.

Label:

(1) Appropriate precautionary labeling cannot be determined until the previously mentioned data is submitted

Reviewer:

(1) Acute Oral Toxicity Study: Monsanto Company; Study # 830018; August 25, 1983.

Procedure: Five male and five female Sprague-Dawley rats weighing between 184 and 249 grams received 5,000 mg/kg of the test material orally. Observations made twice daily for 15 days post treatment. Necropsy performed on all animals.

Results: No mortalities reported. Toxic signs reported included weight loss in one female animal and red nasal discharge; diarrhea in one male rat. No abnormalities reported at necropsy. LD50 reported to be greater than 5000 mg/kg.

Study Classification: Core Guideline Data

Toxicity Category: IV - CAUTION

(2) Acute Dermal Toxicity Study: Monsanto Company; Study # 830019; August 25, 1983.

Procedure: Five male and five female New Zealand rabbits weighing between 2.35 and 2.73 Kg received 5000 mg/Kg of the test material at intact skin sites under occlusive wrap for 24 hour exposure. Observations were made twice daily for 15 days. Necropsy performed on all animals.

Results: No mortalities reported. Toxic signs reported included weight loss and diarrhea. Erythema and edema also reported. At necropsy, fibrous, off-white scarring of hepatic tissue in 3/5 M, multiple yellow hepatic foci in 3/5 M + 4/5 F; areas of off-white discoloration of liver hepatic tissue in 1/5 F; hyperemic blood vessels in the mesentery and abdominal tissues in 4/5 M and tapeworm cysts in the mesentery in 3/5 M and 1/5 F. LD50 greater than 5000 mg/Kg.

Study Classification: Core Guideline Data.

Toxicity Category: IV - CAUTION

(3) Primary Skin Irritation Study: Monsanto Company; Study # 830020; August 25, 1983.

Procedure: Six New Zealand rabbits received 0.5 ml of the test material at intact skin sites under occlusive gauze wrap for four hour exposure. Observations made at 24, 48 and 72 hours after treatment.

Results: ~~at 24 hours or 72 hours~~. No irritation present at 24 or 72 hours after

treatment. Primary Irritation Score was zero.

Study Classification: Core Guideline Data.

Toxicity Category: III - CAUTION

(4) Eye Irritation Study: Monsanto Company; Study # 830021; August 25, 1983.

Procedure: Six New Zealand rabbits received 0.1 ml of the test material in one eye each. Observations were made at 1, 24, 48 and 72 hours after treatment and at 7 days.

Results: at day 1, 4/6 corneal opacity (4/6=5); 6/6 conjunctive redness (5/6=1, 1/6=2), chemosis (3/6=1, 3/6=2) and 4/6 discharge (2/6=1, 1/6=2, 1/6=3). At day 3, 2/6 redness (2/6=1). 1/6 chemosis (1/6=2) and discharge (1/6=1). At day 7, all irritation had cleared.

Study Classification: Core Guideline Data.

Toxicity Category: III - CAUTION

DEC - 5 1983

Monsanto Company
1101 17th Street, NW.
Washington, DC 20036

Attention: S. L. Kimball

Gentlemen:

Subject: Roundup Herbicide (Mouse Oncogenicity Study)
EPA Registration No. 524-308
Shackle Herbicide
EPA Registration No. 524-330
Shackle C Herbicide
EPA Registration No. 524-339 ✓
Polado Herbicide
EPA Registration No. 524-332
Rodeo Herbicide
EPA Registration No. 524-343
Your Submission of August 17, 1983

This acknowledges receipt of your mouse oncogenicity study on glyphosate. Further action will await completion of scientific review and evaluation.

The accession numbers assigned the data are as follows:

Volume 1 of 8	251007
Volume 2 of 8	251008
Volume 3 of 8	251009
Volume 4 of 8	251010
Volume 5 of 8	251011
Volume 6 of 8	251012
Volume 7 of 8	251013
Volume 8 of 8	251014

Sincerely yours,

Robert J. Taylor
Product Manager (25)
Fungicide-Herbicide Branch
Registration Division (TS-767C)

DCR-04333:RD-24:12/01/83:KIM:Del.12/16/83

CONCURRENCES

SYMBOL ▶	TS-767							
SURNAME ▶	VKimball							
DATE ▶	12/5/83							

EPA Form 1320-1 (4-81) OFFICIAL FILE COPY

NOV 28 1983

Monsanto Company
1101 17th Street, NW.
Washington, DC 20036

Attention: S. L. Kimball

Gentlemen:

Subject: Shackle C Herbicide (Shackle C/glyphosate data inventory to conform with PR Notice 83-4)
EPA Registration No. 524-339
Your Letter Dated September 12, 1983

We have your letter of September 12, 1983, transmitting the data inventory for the subject product. This information has been added to the files. The accession number assigned this volume is 251260.

Sincerely yours,

Robert J. Taylor
Product Manager (25)
Fungicide-Herbicide Branch
Registration Division (TS-767C)

DCR-10908:RD-7:11/22/83:KIM:Del:12/3/82

CONCURRENCES								
SYMBOL ▶								
SURNAME ▶								
DATE ▶								

EPA Form 1320-1 (4-81) OFFICIAL FILE COPY

Monsanto

Monsanto Company
1101 17th Street, N. W.
Washington, D. C. 20036
Phone: (202) 452-8860

September 12, 1983

Director
Registration Division (TS767C)
Office of Pesticide Programs
U. S. Environmental Protection Agency
1921 Jefferson Davis Highway
Crystal Mall #2, Room 716D
Arlington, Virginia 22202

Attention: Mr. Robert J. Taylor
Product Manager (25)

Subject: Shackle® C Herbicide
EPA Reg. No. 524-339
Submission of a Shackle C/glyphosate data inventory to conform with the PR 83-4 Interim Registration Procedures. 251260

Dear Sir:

Pursuant to the interim registration procedures of PR Notice 83-4, we hereby submit an inventory of the data that supports the registration of Shackle C herbicide. This data inventory is organized to conform with the data requirements as outlined in 40 CFR 158.

Please note the following comments about this new data inventory:

1. The references for product chemistry (158.120) include several "gaps". We believe that for the following reasons their requirement should be temporarily waived.

   The proposed data requirements for registration (40 CFR 158) were published on 11/24/82. Shortly thereafter, Monsanto began developing a new data base for product chemistry that conforms to the requirements of part 158. This data package will be completed by mid-1984 and submitted to the Agency. We believe that it is reasonable to allow this amount of time to respond to the revised requirements and, hence, request that the product chemistry data presently on file with the Agency be accepted to support proposed registrations until the new studies are completed.

To comply with the requirements of PR 83-4 which are presently impeding glyphosate registrations, we have obtained a letter of certification/data authorization from Chevron, the only other data submitter of record for glyphosate. A copy of their letter is enclosed in the data inventory book.

2. The data format used in part 158 does not include identification of certain data that are important for overall support of the product registration (e.g., applicator exposure studies). We have conformed to the requirements of PR 83-4 by submitting a data inventory under the part 158 format, but have for certain requirements included appendicies of supporting data. Moreover, we have included a copy of the previously used data references which list additional studies that support the registration.

This data inventory document includes all of the data which would be referenced to support a registration for Shackle C or a like product. Because future registration applications will rely on it, we request that it be filed under a specific accession number that can then be referenced with each application. Also, we will be updating this document as new data are submitted and a specific accession number will permit specific filing instructions for the revised data references.

Please let us know the accession number under which this submission is filed. If you have questions or comments about this data inventory, please contact me.

Sincerely,

S L Kimball

Steven L. Kimball
Registration Manager

/pt
Enclosure

cc: C. T. Dickerson/L. L. Gingerich

OCT 25 1983

Monsanto Company
1101 17th Street, NW.
Washington, DC 20036

Attention: S. L. Kimball

Gentlemen:

Subject: Shackle C Herbicide (Acute Toxicology Studies)
EPA Registration No. 524-339
Your Letter Dated September 14, 1983

We have your letter of September 14, 1983, transmitting acute toxicology in support of the subject registration. Further action will await completion of scientific review and evaluation.

The accession number assigned these data is 251442.

Sincerely yours,

Robert J. Taylor
Product Manager (25)
Fungicide-Herbicide Branch
Registration Division (TS-767C)

RD:RJTAYLOR:DCR-10888:RD-7:RAVEN:CBP:10/21/83

CONCURRENCES								
SYMBOL ▶								
SURNAME ▶	VRWatters							
DATE ▶								

EPA Form 1320-1 (4-81) OFFICIAL FILE COPY

Monsanto

Monsanto Company
1101 17th Street, N. W.
Washington, D. C. 20036
Phone: (202) 452-8860

September 14, 1983

Director
Registration Division (TS767C)
Office of Pesticide Programs
U. S. Environmental Protection Agency
1921 Jefferson Davis Highway
Crystal Mall #2, Room 716D
Arlington, Virginia 22202

Attention: Mr. Robert J. Taylor
Product Manager (25)

Subject: Shackle® C Herbicide
EPA Reg. No. 524-339
Acute toxicity data on Shackle C diluted with water to 10% active ingredient.

251442

Dear Sir:

Shackle C herbicide is presently registered for reformulation purposes only. It contains 41% by weight of the active ingredient (AI) isopropylamine salt of glyphosate, and permits formulation of products not to exceed 10% AI.

To date, we have provided the Agency with acute toxicity data for a Shackle C dilution containing 0.96% AI. The Monsanto product using this dilution is named Shackle® (EPA Reg. No. 524-330). Through the "formulator's exemption" and with Monsanto's permission to cite our data, several other companies have also registered glyphosate products containing 0.96% AI. There have also been several instances where product formulations containing up to 10% AI have been requested. However, they have been deferred because acute toxicology on such formulations had not been completed.

Acute toxicity studies are now completed on water dilutions of Shackle C that contain 10% AI of the isopropylamine salt of glyphosate. We are now submitting these studies for your review and files. These studies are intended to support (by specific authorization only) future formulation registrations that contain 10% by weight isopropylamine salt of glyphosate, and that are water dilutions of Shackle C.

Furthermore, when the results of the acute toxicology on Shackle C (10% AI) are compared to the results of similar studies on Shackle (0.96% AI), it is evident that they are sufficiently similar to permit bridging of the data in support of any similar formulation containing from 0.96% to 10.0% AI (see attached table). Neither formulation exceeds a category III classification.

Two (2) copies of new acute toxicology data are enclosed for your review. Please notify me of the accession number for this submission and contact me if you have questions about glyphosate or these data.

Sincerely,

S L Kimball

Steven L. Kimball
Registration Manager

/pt
Enclosures

cc: L. L. Gingerich

DATA SUBMISSION LISTING	Product Name: Shackle® C	EPA Reg. No./File Symbol: 524-339	Page 1 of 1
	Applicant's Name and Address: Monsanto Company, 1101 17th Street, N.W., Washington, D.C. 20036		To accompany application for registration dated: Sept. 14, 1983

NAME OF STUDY	SOURCE OF STUDY: APPLICANT CONDUCTED STUDY	OBTAINED FROM EPA	OBTAINED FROM ANOTHER FIRM OR SOURCE GIVE NAME AND ADDRESS	OBTAINED FROM PUBLIC LITERATURE GIVE REFERENCE	OTHER EXPLAIN	ACCESSION NUMBER EPA USE ONLY
Acute Oral Toxicity of Shackle C Herbicide (Diluted to 10% Isopropylamine Salt of Glyphosate with Water) to Rats [ML-82-017; Study 830018]	X					
Acute Dermal Toxicity of Shackle C Herbicide (Diluted to 10% Isopropylamine Salt of Glyphosate with Water) to Rabbits [ML-83-017; Study 830019]	X					
Primary Skin Irritation of Shackle C Herbicide (Diluted to 10% Isopropylamine Salt of Glyphosate with Water) to Rabbits [ML-83-017; Study 830020]	X					
Primary Eye Irritation of Shackle C Herbicide (Diluted to 10% Isopropylamine Salt of Glyphosate with Water) to Rabbits [ML-83-017; Study 830021]	X					
IF YOU CHECKED THIS COLUMN DO YOU WISH YOUR NAME PLACED ON THE DATA SUBMITTERS LIST? [X] YES [ ] NO						

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

AUG 12 1983

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

Monsanto Company
800 N. Lindbergh Blvd.
St. Louis, MO 63166

SUBJECT: Product Name: Shackle C.
EPA Reg. No. or File Symbol: 524-339
Your Application Dated: 5/17/83

Gentlemen:

The purpose of this letter is to notify you that the subject application will not be processed further until you have complied with the new procedures for satisfying data support requirements. These procedures were explained in PR Notices 83-4 and 83-4A, dated June 16, 1983, which were mailed to you earlier under separate cover.

Since the above notices were sent, the United States Supreme Court has rejected EPA's application to stay the Monsanto district court injunction. Therefore, no further supplement or changes to the data support options provided in PR Notices 83-4 and 4A can be made available at this time. We in EPA are well aware of the difficulties which arise from these court decisions and the complicated procedures established as a result of these decisions. Although these recent actions have placed a heavy burden on our limited resources, we will work with you to continue the registration process to the extent possible. To that end, a shorthand version of the method of data support options set forth in the PR Notices follows:

OVERVIEW OF OPTIONS	PR NOTICE REFERENCES
I. OPTION: Owner Submission Method	(Pg.11 Sect. I)
(Submit a matrix chart (See Attachment A - Sample Matrix) which includes the following items):	
A. List of data requirements applicable to your product. The list must be based on EPA's proposed regulations in 40 CFR Part 158. (See Attachment B - 40 CFR Part 158 and Attachment E Ordering Guidelines.)	(Pgs. 11-13 Sect. IA)
B. How each of those data requirements in "A" are to be satisfied. Possible ways to satisfy these requirements are:	(Pgs. 13-15 Sect. IB)
1. Reference data previously submitted to EPA by you, the applicant.	(Pgs. 13-14 Sect. IB-1)
2. Reference data previously submitted to EPA by someone other than you. (Make sure a letter giving permission for the use of all such referenced data accompanies your application.)	(Pgs. 13-14 Sect. IB-1)
3. Submit data not previously submitted, or submit data from the public literature.	(Pgs. 13-14 Sect. IB-1
4. Document waivers of data previously allowed by EPA. (See Attachment C - waiver list.)	(Pg. 13 Sect. IA-3)
5. Demonstrate that a data gap(s) exist.	(Pgs. 14-15 Sect. IB-2)
6. Indicate each data requirement which is determined not to be applicable based on tier testing.	(Pg. 12) (Last para. of Sect. IA-1)

- OR -

II. OPTION: Total Permission Method (Pg. 15 Sect. IC)

A. Submit a letter which grants you permission to use all relevant data to support your application from each company that appears on the most recent "Data Submitter List" (as of this mailing the most recent list is dated July 19, 1982) for each active ingredient in your product. If your company is the only name that appears on the "Data Submitters List", simply indicate this and state that you are using the Total Permission Method of support.

B. In certain cases EPA may know of other data submitters who should be written to. If this is the case, you will be notified by this office after you have selected your method of support option.

IMPORTANT NOTE: In addition, if you are eligible for the formulator's exemption, (i.e. you are formulating your end-use product from a purchased and registered source), you must submit a completed copy of the form attached to PR Notice 83-4A as Attachment A. You also submit a copy of the Confidential Statement of Formula for each product or cite a current (up to date) Confidential Statement of Formula. (A copy of the Confidential Statement of Formula form is enclosed for your use). (Pg. 12 Sect. IA-2)

Since the PR Notices have been distributed several reoccurring questions have been received. We have included a question and answer sheet (Attachment D) which covers those questions.

Please read the PR Notices 83-4 and 4A thoroughly before making your choice, since much of the detailed information included in those documents is not discussed in this letter. In order to allow you more time than the normal 75 days to return your reply before we treat your application as withdrawn, we are allowing you 150 days from the date of this letter before

your application will be treated as withdrawn. If additional time is required to comply with the provisions of the PR Notice an extension of time should be requested.

If you have any questions after having thoroughly read the PR Notices 83-4 and 4A please call me at (AC 703)-557-1800.

Sincerely yours,

Josie Hollingsworth
for Robert Taylor

Robert Taylor, Manager
Product Team 25
Insecticide-Rodenticide Branch
Registration Division (TS-767C)

Enclosures:

Attachment A - Sample Matrix

Attachment B - 40 CFR Part 158

Attachment C - Waiver List

Attachment D - Question and Answer Sheet

Attachment E - Ordering Guidelines

Confidential Statement of Formula

PAZIANOS ASSOCIATES
E. GEORGE PAZIANOS
211 - 9TH STREET N.E.
WASHINGTON, D.C. 20002

524-339

Robert J. Taylor
Product Manager 25
Registration Div./OPP

May 16, 1983

Dear Bob,

Enclosed is a letter of authorization from Monsanto allowing the use of its data to support the application of the Celex Corporation for a .96% Glyphosate product.

I will appreciate receiving a call at 546-8427 when you have signed the registration so I can arrange to have it picked up.

Warmest regards,

George

E. George Pazianos

46515-L

339

Monsanto

MONSANTO AGRICULTURAL PRODUCTS CO.
800 N. Lindbergh Boulevard
St. Louis, Missouri 63167
Phone: (314) 694-1000

May 11, 1983

REGISTERED MAIL
RETURN RECEIPT REQUESTED

Pazianos Associates
211 9th Street, N.E.
Washington, D.C. 20002

Attention: Mr. George Pazianos

Dear Mr. Pazianos:

This is to acknowledge receipt of your letter dated March 2, 1983 in connection with the application of Celex Corporation for EPA registration of Super K-Gro Ready to Use Systemic Weed & Grass Killer (.96%) which you have filed as an agent for Celex. Please be advised that Monsanto Company authorizes the Environmental Protection Agency ("EPA") to refer to data in our files on Shackle® C herbicide (EPA Reg. No. 524-339) in support of the application specified in the preceding sentence.

This letter is an authorization for only EPA personnel to refer to Monsanto's files regarding Monsanto's aforementioned pesticide on a confidential basis solely in support of said application. None of the data in these files is to be released to your company.

Very truly yours,

MONSANTO COMPANY

By Frank S. Serdy
Frank S. Serdy

Manager, Registration
(Title)

CATS
14443

AUG 27 1981

Monsanto Company
1101 17th Street, N.W.
Washington, D.C. 20036

Attention: Glynadee Edwards

Gentlemen:

Subject: Shackle(R) C
EPA Registration No. 524-339

This will acknowledge receipt of your submission of August 17, 1981 informing us of the bulk labeling for this product. The label submitted has been made a part of the records for this file.

Sincerely,

Robert J. Taylor
Product Manager (25)
Fungicide-Herbicide Branch
Registration Division (TS-767)

TS-767:TAYLOR:DCR# 35503:Wang 0797B:RAVEN:8/25/81

Monsanto

Monsanto Company
1101 17th Street, N.W.
Washington, D.C. 20036
Phone: (202) 452-8880

August 17, 1981

Director
Registration Division (TS767C)
Office of Pesticide Programs
U. S. Environmental Protection Agency
1921 Jefferson Davis Highway
Arlington, Virginia 22202

Attention: Mr. Robert J. Taylor
Product Manager (25)

Subject: Shackle® C
EPA Reg. No. 524-339
Bulk Labels

Dear Sir:

On September 16, 1980, the Agency approved a 54-gallon container label for Shackle® C herbicide. At this time we are requesting a bulk label for Shackle C. We plan to use the 54-gallon label, but will omit the "54 U.S. gallon." There will be less than ten bulk shipments made per year, hence, we do not wish to generate a separate label.

Enclosed are five (5) copies of the bulk labels for your approval.

If you have questions, please contact us.

Sincerely,

Glynadee Edwards

Glynadee Edwards
Registration Specialist

GE:jr
Enclosures

cc: Dr. J. T. Richardson

8/21/81

The Chas. H. LILLY Co.
LILLY/MILLER

7737 N.E. KILLINGSWORTH • PORTLAND, OREGON 97218 • (503) 256-4600

July 9, 1981

U. S. Environmental Protection Agency
Registration Division (TS-767C)
401 M Street, S. W.
Washington, D. C. 20460

Attn: Mr. Robert J. Taylor, PM 25
Fungicide-Herbicide Branch
Room 412E, CM #2

Gentlemen:

Subject: Our letter June 15, 1981 - Application for a New Registration - Lilly/Miller KNOCKOUT Weed & Grass Killer

Enclosed is copy of letter just received from Monsanto Agricultural Products Co. (July 6, 1981) sent in support of our above referred to product.

We trust that with this information, our Application will be given prompt attention. Thank you for your considerations.

Very truly yours,

Frank B. Stewart

Frank B. Stewart
Vice President

K

5200 DENVER AVENUE S. • SEATTLE, WASH. 98108 • (206) 762-0818
9919 EAST MONTGOMERY • SPOKANE, WASH. 99206 • (509) 922-3333

Monsanto

MONSANTO AGRICULTURAL PRODUCTS CO.
800 N. Lindbergh Boulevard
St. Louis, Missouri 63166
Phone (314) 694-1000

July 6, 1981

REGISTERED MAIL
RETURN RECEIPT REQUESTED

The Chas. H. Lilly Co.
7737 N.E. Killingsworth
Portland, Oregon 97218

ATTN: Mr. Frank B. Stewart

Dear Mr. Stewart:

This is to acknowledge receipt of your letter dated June 15, 1981. Please be advised that Monsanto Company authorizes the Environmental Protection Agency ("EPA") to refer to data in our files on Shackle® C, EPA Reg. No. 524-339, in support of your registration of Knockout Weed & Grass Killer.

This letter is an authorization for only EPA personnel to refer to Monsanto's files regarding Monsanto's aforementioned pesticide on a confidential basis solely in support of said application. None of the data in these files is to be released to your company.

Monsanto has filed suit against the EPA, challenging the legality and enforceability of Sections 3(c)(1)(D), 3(c)(2), and 10 of the Federal Insecticide, Fungicide, and Rodenticide Act, as amended ("FIFRA"). Therefore, this letter is not to be construed as an admission by Monsanto concerning the legality or enforceability of Sections 3(c)(1)(D), 3(c)(2), and 10 of FIFRA and any regulations promulgated thereunder, or as a waiver of Monsanto's right to challenge said legality or enforceability. Nor is it to be construed as a waiver of Monsanto's right to require compensation for the use of said data, or any other data submitted by Monsanto.

Sincerely yours,

MONSANTO COMPANY

By Frank S. Serdy
Frank S. Serdy

Manager, Registration
(Title)

/pt

U.S. ENVIRONMENTAL PROTECTION AGENCY
OFFICE OF PESTICIDES PROGRAMS
REGISTRATION DIVISION *(WH-567)*
WASHINGTON, D.C. 20460

NOTICE OF PESTICIDE: ☐ REGISTRATION ☐ REREGISTRATION

(Under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended)

EPA REGISTRATION NO.	DATE OF ISSUANCE
524-339	9/24/80

TERM OF ISSUANCE: Conditional Registration

NAME OF PESTICIDE PRODUCT: Shackle C.

NAME AND ADDRESS OF REGISTRANT *(Include ZIP code)*

Monsanto Company
800 N. Lindbergh Blvd.
St. Louis, MO 63166

NOTE: Changes in labeling formula differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Registration Division prior to use of the label in commerce. In any correspondence on this product always refer to the above U.S. EPA registration number.

On the basis of information furnished by the registrant, the above named pesticide is hereby Registered/Reregistered under the Federal Insecticide, Fungicide, and Rodenticide Act.

A copy of the labeling accepted in connection with this Registration/Reregistration is returned herewith.

Registration is in no way to be construed as an indorsement or approval of this product by this Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.

This product is conditionally registered in accordance with the provisions of Section 3(c)(7)(A) of the Act, since you have agreed that you will submit and/or cite all data required for registration/reregistration of your product under FIFRA Section 3(c)(5) when the Agency requires all registrants of similar products to submit such data.

If these conditions are not complied with, the registration will be subject to cancellation in accordance with Section 6(e) of the Act.

Sincerely,

Robert Taylor
Product Manager (25)
Fungicide-Herbicide Branch
Registration Division (TS-767)

☐ ATTACHMENT IS APPLICABLE

SIGNATURE OF APPROVING OFFICIAL	DATE
	11-4-80

EPA Form 8570-6 (Rev. 5-76) PREVIOUS EDITION MAY BE USED UNTIL SUPPLY IS EXHAUSTED.

LIMIT OF WARRANTY AND LIABILITY

This company warrants that this product conforms to the chemical description on this label. NO OTHER EXPRESS OR IMPLIED WARRANTY OF FITNESS FOR PARTICULAR PURPOSE OR MERCHANTABILITY IS MADE. This warranty is also subject to the conditions and limitations stated herein.

Buyer and all users shall promptly notify this company of any claims whether based in contract, negligence, strict liability, other tort or otherwise.

Buyer and all users are responsible for all loss or damage from use or handling which results from conditions beyond the control of this company, including but not limited to uses or applications in any manner not explicitly set forth in this label or application to or contact with desirable vegetation.

THE EXCLUSIVE REMEDY OF THE USER OR BUYER, AND THE LIMIT OF THE LIABILITY OF THIS COMPANY OR ANY OTHER SELLER FOR ANY AND ALL LOSSES, INJURIES OR DAMAGES RESULTING FROM THE USE OR HANDLING OF THIS PRODUCT (INCLUDING CLAIMS BASED IN CONTRACT, NEGLIGENCE, STRICT LIABILITY, OTHER TORT OR OTHERWISE) SHALL BE THE PURCHASE PRICE PAID BY THE USER OR BUYER FOR THE QUANTITY OF THIS PRODUCT INVOLVED, OR, AT THE ELECTION OF THIS COMPANY OR ANY OTHER SELLER, THE REPLACEMENT OF SUCH QUANTITY OR, IF NOT ACQUIRED BY PURCHASE, REPLACEMENT OF SUCH QUANTITY. IN NO EVENT SHALL THIS COMPANY OR ANY OTHER SELLER BE LIABLE FOR ANY INCIDENTAL OR CONSEQUENTIAL DAMAGES.

The buyer and all users are deemed to have accepted the terms of this LIMIT OF WARRANTY AND LIABILITY which may not be varied by any verbal or written agreement.

U.S. Pat. No. 3,799,758 covers use. Other patents are pending.

In case of an emergency involving this product, Call Collect, day or night, (314) 694-4000.

MONSANTO COMPANY
AGRICULTURAL PRODUCTS
ST. LOUIS, MISSOURI 63166 U.S.A.

346

It is a violation of Federal Law to use this product in any manner inconsistent with its labeling.

Read the entire label.

PRECAUTIONARY STATEMENTS

Hazard to Humans and Domestic Animals

WARNING!

Keep out of reach of children.

CAUSES EYE IRRITATION.

HARMFUL IF SWALLOWED.

Do not get in eyes, on skin or on clothing.

FIRST AID: In case of contact, immediately flush eyes with plenty of water for at least 15 minutes. Call a physician. Flush skin with water. Wash clothing before reuse.

Physical or Chemical Hazards

Solutions of this product should be mixed and stored only in stainless steel, aluminum, fiberglass, plastic and plastic-lined steel containers.

DO NOT MIX OR STORE THIS PRODUCT OR SOLUTIONS OF THIS PRODUCT IN GALVANIZED STEEL OR UNLINED STEEL (EXCEPT STAINLESS STEEL) CONTAINERS OR SPRAY TANKS.
This product or solutions of this product react with such containers and tanks to produce hydrogen gas which may form a highly combustible gas mixture. This gas mixture could flash or explode, causing serious personal injury, if ignited by open flame, spark, welder's torch, lighted cigarette, or other ignition source.

Environmental Hazards

Keep out of lakes, streams and ponds. Do not contaminate water by disposal of waste or cleaning of equipment.

Storage and Disposal

Avoid contamination of seed, feed and food stuffs.

Emptied container retains vapor and product residue. Observe all labeled safeguards until container is cleaned, reconditioned or destroyed. DO NOT CUT OR WELD ON OR NEAR THIS CONTAINER.

13

CONCENTRATE

SHACKLE® C

HERBICIDE BY **Monsanto**

ACCEPTED
SEP 24 1980
Under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, for the pesticide registered under EPA Reg. No. 524-358

For formulation of products (not to exceed 10% active ingredient) for weed and grass control in home lawns and gardens.

Read "LIMIT OF WARRANTY AND LIABILITY" before buying or using. If terms are not acceptable, return at once unopened.

Read precautions on side panel.

WARNING!
Keep out of reach of children.

Active Ingredient:	
*Isopropylamine salt of Glyphosate	41.0%
Inert Ingredients:	59.0%
	100.0%

*Contains 480 grams per liter or 4 pounds of the active ingredient isopropylamine salt of N-(phosphonomethyl) glycine per U.S. gallon. Equivalent to 356 grams per liter or 3 pounds per U.S. gallon of the acid, glyphosate.

NET 54 U.S. GAL.

EPA Reg. No. 524-14

EPA Est. 524-LA-1

2233/53

LIMIT OF WARRANTY AND LIABILITY

This company warrants that this product conforms to the chemical description on this label. NO OTHER EXPRESS OR IMPLIED WARRANTY OF FITNESS FOR PARTICULAR PURPOSE OR MERCHANTABILITY IS MADE. This warranty is also subject to the conditions and limitations stated herein.

Buyer and all users shall promptly notify this company of any claims whether based in contract, negligence, strict liability, other tort or otherwise.

Buyer and all users are responsible for all loss or damage from use or handling which results from conditions beyond the control of this company, including but not limited to uses or applications in any manner not explicitly set forth in this label or application to or contact with desirable vegetation.

THE EXCLUSIVE REMEDY OF THE USER OR BUYER, AND THE LIMIT OF THE LIABILITY OF THIS COMPANY OR ANY OTHER SELLER FOR ANY AND ALL LOSSES, INJURIES OR DAMAGES RESULTING FROM THE USE OR HANDLING OF THIS PRODUCT (INCLUDING CLAIMS BASED IN CONTRACT, NEGLIGENCE, STRICT LIABILITY, OTHER TORT OR OTHERWISE) SHALL BE THE PURCHASE PRICE PAID BY THE USER OR BUYER FOR THE QUANTITY OF THIS PRODUCT INVOLVED, OR, AT THE ELECTION OF THIS COMPANY OR ANY OTHER SELLER, THE REPLACEMENT OF SUCH QUANTITY OR, IF NOT ACQUIRED BY PURCHASE, REPLACEMENT OF SUCH QUANTITY. IN NO EVENT SHALL THIS COMPANY OR ANY OTHER SELLER BE LIABLE FOR ANY INCIDENTAL OR CONSEQUENTIAL DAMAGES.

The buyer and all users are deemed to have accepted the terms of this LIMIT OF WARRANTY AND LIABILITY which may not be varied by any verbal or written agreement.

U.S. Pat. No. 3,799,758 covers use. Other patents are pending.

In case of an emergency involving this product, Call Collect, day or night, (314) 694-4000.

MONSANTO COMPANY
AGRICULTURAL PRODUCTS
ST. LOUIS, MISSOURI 63166 U.S.A.

It is a violation of Federal Law to use this product in any manner inconsistent with its labeling.

Read the entire label.

PRECAUTIONARY STATEMENTS

Hazard to Humans and Domestic Animals

WARNING!

Keep out of reach of children.

CAUSES EYE IRRITATION.

HARMFUL IF SWALLOWED.

Do not get in eyes, on skin or on clothing.

FIRST AID: In case of contact, immediately flush eyes with plenty of water for at least 15 minutes. Call a physician. Flush skin with water. Wash clothing before reuse.

Physical or Chemical Hazards

Solutions of this product should be mixed and stored only in stainless steel, aluminum, fiberglass, plastic and plastic-lined steel containers.

DO NOT MIX OR STORE THIS PRODUCT OR SOLUTIONS OF THIS PRODUCT IN GALVANIZED STEEL OR UNLINED STEEL (EXCEPT STAINLESS STEEL) CONTAINERS OR SPRAY TANKS.
This product or solutions of this product react with such containers and tanks to produce hydrogen gas which may form a highly combustible gas mixture. This gas mixture could flash or explode, causing serious personal injury, if ignited by open flame, spark, welder's torch, lighted cigarette, or other ignition source.

Environmental Hazards

Keep out of lakes, streams and ponds. Do not contaminate water by disposal of waste or cleaning of equipment.

Storage and Disposal

Avoid contamination of seed, feed and food stuffs.

Emptied container retains vapor and product residue. Observe all labeled safeguards until container is cleaned, reconditioned or destroyed. DO NOT CUT OR WELD ON OR NEAR THIS CONTAINER.

CONCENTRATE

SHACKLE® C

HERBICIDE BY **Monsanto**

For formulation of products (not to exceed 10% active ingredient) for weed and grass control in home lawns and gardens.

Read "LIMIT OF WARRANTY AND LIABILITY" before buying or using. If terms are not acceptable, return at once unopened.

Read precautions on side panel.

Active Ingredient:	
*Isopropylamine salt of Glyphosate	41.0%
Inert Ingredients:	59.0%
	100.0%

*Contains 480 grams per liter or 4 pounds of the active ingredient isopropylamine salt of N-(phosphonomethyl) glycine per U.S. gallon. Equivalent to 356 grams per liter or 3 pounds per U.S. gallon of the acid, glyphosate.

8/21/81

EPA Reg. No. 524-339

EPA Est. 524-LA-1

2233 53

WARNING!

Keep out of reach of children.

NET

Monsanto

Monsanto Company
1101 17th Street, N.W.
Washington, D.C. 20036
Phone: (202) 452-8880

September 24, 1980

Director
Registration Division (TS-767)
Environmental Protection Agency
Waterside Mall, East Tower
Washington, D. C. 20460

Attention: Mr. Robert J. Taylor
Product Manager (25)

Subject: Shackle - C™
Registration of a New Product

Dear Sir:

On September 23, 1980, the EPA notified Monsanto by telephone that the agency had accepted the registration for Shackle - C™, a glyphosate formulation to be used for reformulation only, provided Monsanto completes one additional requirement. We hereby submit the required information to complete this registration:

1. Monsanto agrees to submit and/or cite all data required for registration/reregistration of these products under FIFRA Section 3(c)(5) when the Agency requires all registrants of similar products to submit such data.

Please contact us at Monsanto if you have questions regarding this registration.

Sincerely,

John T. Richardson
Government Affairs Manager

/ms

cc: Frank Serdy

SUBMISSION REVIEW RECORD G

1. REGISTRATION NUMBER	CYCLE	2. DATE RECEIVED
524-GGO		MO 09 DAY 22 YR 80

3. 3CID PUBLICATION NECESSARY	4. PETITION NO.	5. RECEIVED PM TEAM
☐ YES ☐ NO		MO DAY YR

6. METHOD OF SUPPORT	7. PRODUCT MANAGER	NO.	8. PROJECTED RETURN
☐ 2A ☐ 2B ☐ 2C	Taylor	25	MO DAY YR

9. DATE PULLED	10. DATE PUBLISHED	11. ACTION TYPE	CODE	12. OUTGOING DATE
		170		MO DAY YR

REV. SEQ.	REVIEW TYPE CODE	REVIEW TYPE	REVIEWER CODE (Initials)	SIGNATURE OF REVIEWER	COMMENT CODE	DATE REVIEW COMPLETED MO	DAY	YR
X	A	REVIEWABILITY TEAM		Anna Cowtlakis	NAC	09	22	80
	B	PRODUCT MANAGER TEAM EFFICACY REVIEW						
	C	PRODUCT MANAGER TEAM HUMAN SAFETY REVIEW						
	D	PRODUCT MANAGER TEAM ENVIRONMENTAL SAFETY REVIEW						
X	E	PRODUCT MANAGER TEAM RESUBMISSION REVIEW		Jackie Bruder				
	F	PRODUCT MANAGER						
	G	INTERAGENCY REFERRAL						
	H	COST-BENEFIT REVIEW						
	I	PUBLIC COMMENTS REVIEW						
	J	EEE BRANCH INSECTICIDE EFFICACY						
	K	EEE BRANCH HERBICIDE EFFICACY						
	L	EEE BRANCH FUNGICIDE EFFICACY						
	M	EEE BRANCH RODENTICIDE EFFICACY						
	N	EEE BRANCH DISINFECTANT EFFICACY						
	O	CHEMISTRY BRANCH RESIDUE CHEMISTRY						
	P	EEE BRANCH ENVIRONMENTAL CHEMISTRY						
	Q	TOXICOLOGY BRANCH HUMAN SAFETY						
	R	EEE BRANCH ENVIRONMENTAL SAFETY						
	S							
	T							

PRODUCT MANAGER SIGNATURE	TYPE OF RESPONSE	CODE

CHEMISTRY REVIEW

DATE:

SUBMITTED 9-16-80 REVIEW STARTED 9-22-80

REC'D BY DIV. 9-22-80 REVIEW COMPLETED 9-22-80

REC'D BY CHEM. 9-22-80

SUBJECT: EPA FILE SYMBOL 524-GGO APPLICANT: Monsanto

FROM: FHB/TSS Anna Cowtlakis Shackle C

TO: TEAM 25

SUBMISSION PURPOSE New Application

FILE(S) REFERENCED:

ACTIVE INGREDIENT(S)

Isopropylamine salt of Glyphosate 41.0%

COMMENTS: NAC

Note:

1.) Shackle C is monsanto's manufacturing use product which has the same formula as its end use product, Round-Up.

2.) There are [redacted] tertiary alkyl amines being used as inerts in this product which were cleared by Bob Taylor when Mr. Richardson of Monsanto told him that nitrosamine analysis had been done on the formulations containing them.

10

Manufacturing process information may be entitled to confidential treatment

6

Monsanto

Monsanto Company
1101 17th Street, N.W.
Washington, D.C. 20036
Phone: (202) 452-8880

September 16, 1980

Director
Registration Division (TS-767)
Environmental Protection Agency
Waterside Mall, East Tower
Washington, D.C. 20460

Attn: Mr. Robert J. Taylor
Product Manager (25)

Subject: Shackle C™
Application for Registration
of a New Product.

Dear Sir:

Monsanto's herbicide product Roundup® is presently registered with the EPA (EPA Reg. No. 524-308). It is approved for use on many agricultural crops and also for non-crop applications. The active ingredient in Roundup is the isopropylamine salt of glyphosate. Shackle®, another formulation of IPA-glyphosate, was developed as a diluted or ready-to-use product and is also registered with the Agency (EPA Reg. No. 524-330).

Other companies have requested permission from Monsanto to reformulate Roundup into dilute, ready-to-use products. Monsanto will consider these requests on a case-by-case basis. However, it is necessary to register a product label which will permit such reformulation in order for any other company to legally reformulate the IPA-glyphosate product currently made by Monsanto.

Monsanto requests that a new product, named Shackle C, be registered by the EPA. This new product is of the same composition as Roundup herbicide, but is to be labeled solely for the purpose of reformulation by those companies permitted by Monsanto to manufacture a ready-to-use glyphosate product. Five copies of the label are also enclosed.

Completed Application Forms, Offer-to-Pay and Certification Statements, Confidential Statement of Formula, and two data books are enclosed for your files. Please note that all pertinent data on glyphosate is referenced in the petitions.

1 of 15

Director
Registration Division (TS-767)
Environmental Protection Agency

Please contact us at Monsanto if you have questions regarding this application.

Sincerely,

S L Kimball

Steven L. Kimball
Registration Manager

/pt
Enclosures

cc: Dr. J. T. Richardson

REVISED 8/16/79

8

OFFER TO PAY STATEMENT ---- CITE-ALL METHOD OF SUPPORT

EPA File Symbol/Registration Number 524- Date of application 9-16-80

Product Name Shackle C

Applicant's Name and Address Monsanto
800 North Lindbergh Blvd
St. Louis, Mo. 63166

THIS IS AN OFFER TO PAY COMPENSATION UNDER 40 CFR 162.9-4 and -5 IN CONNECTION WITH AN APPLICATION FOR REGISTRATION.

Applicant offers and agrees to pay compensation to other persons with regard to the approval of this application, to the extent required by Sections 3(c)(1)(D) and 3(c)(2)(D) of the Federal Insecticide, Fungicide, and Rodenticide Act, as amended (FIFRA).

Applicant acknowledges that for purposes of FIFRA 3(c)(1)(D) this application, and any resulting registration, relies on the following data:

1. Any data submitted or specifically cited by the applicant. (INCLUDE WITH YOUR APPLICATION THE DATA SUBMISSION LISTING).

2. Each other item of data in the Agency's files which:

   a. Concerns the properties or effects of:

      (1) Applicant's product;
      (2) A product identical or substantially similar in composition to applicant's product; or
      (3) One or more of the active ingredients of applicant's product for which EPA has not published a final generic standard; and

   b. Is one of the types of data that EPA would require to be submitted for scientific review if the application sought the initial registration under FIFRA Section 3(c)(5) of a product with composition and uses identical or substantially similar to those of the applicant's product, under the data requirements in effect on the date EPA approves applicant's present application.

☒ I have notified the appropriate companies and attached the Certification Statement.

☐ The Certification Statement will be submitted prior to registration.

Signature and Title John M Richardson - Gov. Affairs Mgr

Typed name _____ Date signed 9-16-80

CERTIFICATION STATEMENT

EPA File Symbol/ Reg. No. 524- Date of application to which this statement applies 9/16/80

Product Name Shackle C

Applicant's Name and Address Monsanto Company
800 N. Lindbergh Blvd.
St. Louis, Missouri 63166

I certify that I have notified in writing the companies (except those with whom I have reached written agreement) who have submitted data upon which I have relied to support my application and offered to:

1. Pay compensation for those data in accordance with Sections 3(c)(1)(D) and 3(c)(2)(D) of the Federal Insecticide, Fungicide and Rodenticide Act, as amended; and

2. Commence negotiations to determine which data are subject to the compensation requirements of FIFRA, and the amount and terms of compensation, if any, due.

The companies I have notified are:

[X] All companies listed on the Pesticide Data Submitters List for all active ingredients contained in my product (see 40 CFR 162.9-5). (Check this box only if you are using the "cite-all" method of support.)

[ ] All companies listed on the Pesticide Data Submitters List for all active ingredients contained in my product which are not derived from registered and purchased products (see 40 CFR 162.9-8(f)). (Check this box only if you are using the "combined" method of support.)

[ ] Those companies who have conducted the studies which I have submitted (or cited if conducted with an identical product)(see 40 CFR 162.9-8(e)). (Check this box if you are using either the "alternate" method of support or the "combined" method of support.)

Signature and Title S L Kimball Registration Manager

Typed name Steven L. Kimball Date signed 9/16/80

(over)

APPLICANT'S EXECUTION AND SUBMISSION OF THIS FORM IS SOLELY TO OBTAIN AGENCY APPROVAL OF APPLICANT'S REQUEST FOR REGISTRATION AND IS NOT TO BE CONSTRUED AS AN ADMISSION BY APPLICANT THAT THE AGENCY HAS ANY LEGAL AUTHORITY TO REQUIRE APPLICANT TO EXECUTE AND SUBMIT THIS FORM OR AS AN ADMISSION BY APPLICANT CONCERNING THE LEGALITY OR ENFORCEABILITY OF FIFRA, AS AMENDED, OR ANY REGULATIONS PROMULGATED THEREUNDER OR AS A WAIVER OF APPLICANT'S RIGHT TO CHALLENGE SAID LEGALITY OR ENFORCEABILITY.

"This deletion is to comply with the EPA's letter to Monsanto dated April 20, 1979."

SLK
9/16/80

OFFER TO PAY STATEMENT ---- COMBINED CITE-ALL AND ALTERNATE METHODS OF SUPPORT

10

EPA File Symbol/Registration Number 524- Date of Application

Product Name Shackle C

Applicant's Name and Address Monsanto Company

800 N. Lindbergh Blvd.

St. Louis, Missouri 63166

THIS IS AN OFFER TO PAY COMPENSATION UNDER 40 CFR 162.9-8 IN CONNECTION WITH REGISTRATION OF AN END-USE PRODUCT WHICH WILL CONTAIN ONE OR MORE ACTIVE INGREDIENT(S) DERIVED FROM 1) AN UNREGISTERED PRODUCT OR 2) A REGISTERED PRODUCT THAT IS NOT PURCHASED FROM ANOTHER PRODUCER.

Applicant offers and agrees to pay compensation to other persons with regard to the approval of this application to the extent required by Sections 3(c)(1)(D) and 3(c)(2)(D) of the Federal Insecticide, Fungicide and Rodenticide Act, as amended (FIFRA).

Applicant acknowledges that for the purposes of FIFRA Section 3(c)(1)(D), this application relies on, and the Agency shall consider only, the following data:

1. Data submitted by the applicant and conducted using the applicant's formulated product or another product of identical composition. Data already in Agency files which were conducted with a product of identical composition may be cited instead of submitted. (INCLUDE WITH YOUR APPLICATION THE DATA SUBMISSION LISTING.)

2. Existing tolerances, food additive regulations, exemptions, and other clearances issued under the Federal Food, Drug, and Cosmetic Act;

3. With respect to those active ingredients which are derived from registered and purchased products, other data pertaining to the safety of the active ingredient, rather than to the safety of the end-use product (however, under FIFRA 3(c)(2)(D), no compensation is payable for such data); and

4. With respect to those active ingredients which are not derived from registered and purchased products, each item of data in the Agency's files which concerns the properties or effects of any such active ingredient and is one of the types of data that EPA would require to be submitted for scientific review if the applicant sought the initial registration under FIFRA Section 3(c)(5) of a product with composition and intended uses identical to those proposed for the applicant's product, under the data requirements in effect on the date EPA approves the applicant's present application.

The following active ingredients in this product are derived from unregistered products or products that are registered but not purchased from another producer:

[XX] I have notified the appropriate companies and attached the Certification Statement.

[ ] The Certification Statement will be submitted prior to registration.

5

Signature and Title S L Kimball Registration Manager

Typed Name Steven L. Kimball Date signed 9/14/8

(over)

APPLICANT'S EXECUTION AND SUBMISSION OF THIS FORM IS SOLELY TO OBTAIN AGENCY APPROVAL OF APPLICANT'S REQUEST FOR REGISTRATION AND IS NOT TO BE CONSTRUED AS AN ADMISSION BY APPLICANT THAT THE AGENCY HAS ANY LEGAL AUTHORITY TO REQUIRE APPLICANT TO EXECUTE AND SUBMIT THIS FORM OR AS AN ADMISSION BY APPLICANT CONCERNING THE LEGALITY OR ENFORCEABILITY OF FIFRA, AS AMENDED, OR ANY REGULATIONS PROMULGATED THEREUNDER OR AS A WAIVER OF APPLICANT'S RIGHT TO CHALLENGE SAID LEGALITY OR ENFORCEABILITY.

"This deletion is to comply with the EPA's letter to Monsanto dated April 20, 1979."

SLK
9/16/80

DATA SUBMISSION LISTING

Product Name: Shackle C

EPA [redacted] No./File Symbol: 524-

Page 1 of 1

Applicant's Name and Address:
Monsanto Company
800 N. Lindbergh Blvd.
St. Louis, Missouri 63166

To accompany application for registration dated

NAME OF STUDY	SOURCE OF STUDY: APPLICANT CONDUCTED STUDY	OBTAINED FROM EPA	OBTAINED FROM ANOTHER FIRM OR SOURCE GIVE NAME AND ADDRESS	OBTAINED FROM PUBLIC LITERATURE GIVE REFERENCE	OTHER EXPLAIN	ACCESSION NUMBER EPA USE ONLY

IF YOU CHECKED THIS COLUMN — DO YOU WISH YOUR NAME PLACED ON THE DATA SUBMITTERS LIST?
☐ YES ☐ NO

358

Form Approved
OMB No. 158-R0066 12

U.S. ENVIRONMENTAL PROTECTION AGENCY
OFFICE OF PESTICIDES PROGRAM (WH-567)
WASHINGTON, D.C. 20460

APPLICATION FOR PESTICIDE: [X] REGISTRATION [ ] REREGISTRATION

(Please read instructions on reverse before completing) A

1. REFERENCE CODE: NA

2. EPA USE ONLY

3. COMPANY/PRODUCT NO.: 524- GGO

4. PROPOSED CLASSIFICATION
[X] GENERAL [ ] RESTRICTED

5. NAME AND ADDRESS OF APPLICANT (Include ZIP Code)

Monsanto Company
800 N. Lindbergh Blvd.
St. Louis, Missouri 63166

[ ] CHECK IF THIS IS A NEW ADDRESS

6. TYPE OF CONTAINER
[X] METAL
[X] PLASTIC
[ ] GLASS
[ ] PAPER
[ ] OTHER (Specify)

7. WILL CHILD RESISTANT PACKAGING BE USED?
[ ] YES [X] NO

8. PRODUCT NAME: Shackle C

9. EXPERIMENTAL PERMIT NO.

10. LOCATION OF LABEL DIRECTIONS
[ ] ON LABEL
[X] ON MATERIAL ACCOMPANYING PRODUCT

11. MANNER IN WHICH LABEL IS AFFIXED TO PRODUCT
[ ] LITHOGRAPH [ ] OTHER (Specify)
[X] PAPER GLUED
[ ] STENCILED

12.	TYPES OF DATA SUBMITTED		FOR EPA USE ONLY
X	01. NONE	1201	
	02. PRODUCT CHEMISTRY	1202	
	03. RESIDUE CHEMISTRY	1203	
	04. ENVIRONMENTAL CHEMISTRY	1204	
	05. EFFICACY	1205	
	06. PHYTOTOXICITY	1206	
	07. HUMAN SAFETY	1207	
	08. DOMESTIC ANIMAL SAFETY	1208	
	09. FISH AND WILDLIFE SAFETY	1209	
	10. BENEFICIAL INSECT SAFETY	1210	
	11. ACCIDENT EXPOSURE EXPERIENCE	1211	
	12. OTHER (Specify)	1212	
	13. OTHER (Specify)	1213	

13. METHOD OF SUPPORT (See instructions)
[ ] Required Supporting Data Attached. (2A)
[ ] Required Supporting Data is Submitted by Reference. (2B)

14. CONTACT POINT
Complete items directly below for identification of individual to be contacted, if necessary, to process this application.

15. DATE APPLICATION RECEIVED (Stamped)

OFFER TO PAY STATEMENT

I hereby offer to pay reasonable compensation to the extent provided under Section 3(c)(1)(D) of the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, and in accordance with the Regulations and Guidlines published thereunder for use of any test data which has been submitted to the U.S. Environmental Protection Agency in support of an application for the registration of a pesticide for the first time on or after January 1, 1970 and which may be used in support of the registration application for the subject pesticide.

NAME: Steven L. Kimball

TITLE: Registration Manager

TELEPHONE NO. (Include Area Code): (314) 694-3284

16. SIGNATURE: S L Kimball

17. TITLE: Registration Mgr.

18. TYPED NAME: Steven L. Kimball

19. DATE SIGNED: 9/16/80

EPA Form 8570-1 (Rev. 4-76) PREVIOUS EDITION IS OBSOLETE.

Form Approved
OMB No. 158-R0066 13

U.S. ENVIRONMENTAL PROTECTION AGENCY
OFFICE OF PESTICIDE PROGRAMS (WH-567)
WASHINGTON, D.C. 20460

LABEL TECHNICAL DATA

(See INSTRUCTIONS on back of last part)

F

1. COMPANY/REGISTRATION NO.
Monsanto
524- GGO

2. EPA USE ONLY
— —

3. PRODUCT NAME
Shackle C

4. APPLICATION SITES (Check all that apply)		5. PEST TYPE (Check all that apply)		7. USER TYPE (Check all that apply)	
	01 CROPS (Fruit)		01 ALGAE		01 UNSPECIFIED GENERAL USE
	02 CROPS (Vegetable)		02 AMPHIBIAN/REPTILE		02 UNSPECIFIED RESTRICTED USE
	03 CROPS (Field)		03 BACTERIA		03 HOMEOWNER USE
	04 CROPS (Spice)		04 BIRDS		04 JANITORIAL USE
	05 CROPS (Nut)		05 FISH		05 PEST CONTROL OPERATOR USE
	09 CROPS (Other)		06 FOULING ORGANISMS		06 COMMERCIAL APPLICATOR USE
	10 SOIL TREATMENT (No crop specified)		07 FUNGI		07 FARMER USE
	20 FOREST		08 INSECTS AND MITES		08 MEDICAL USE
	30 ORNAMENTALS		09 MAMMALS		09 VETERINARY USE
	40 TURF		10 NEMATODES		10 GOVERNMENT AGENCY USE
	50 STORED PRODUCTS TREATMENT		11 PLANTS	X	11 MANUFACTURING USE
	61 ANIMALS (Livestock)		12 RODENTS	8.	FORMULATION (Check one only)
	62 ANIMALS (Dairy)		13 SLIME		
	63 ANIMALS (Pet)		14 SLUGS AND SNAILS		01 TECHNICAL CHEMICAL
	64 ANIMALS (Laboratory)		15 VIRUS	X	02 FORMULATION INTERMEDIATE
	69 ANIMALS (Other)		16 OTHER (Specify)		03 DUST
	71 OUTDOOR (Nocrop Agricultural)				04 GRANULAR
	72 OUTDOOR (Resident/Commercial)				05 PELLETED/TABLETTED
	73 OUTDOOR (Non agricultural)				06 WETTABLE POWDER
	81 BUILDINGS (Agricultural)	6.	MODE OF ACTION (Check all that apply)		07 WETTABLE POWDER/DUST
	82 BUILDINGS (Commercial)				08 CRYSTALLINE
	83 BUILDINGS (Food Processing)		01 ATTRACTANT		09 MICROENCAPSULATED
	84 BUILDINGS (Medical)		02 BIOLOGICAL CONTROL		10 IMPREGNATED MATERIALS
	85 BUILDINGS (Residential)		03 CHEMOSTERILANT		11 SELF-GENERATING SMOKE
	91 EQUIPMENT (Commercial)		04 DEFOLIANT		12 EMULSIFIABLE CONCENTRATE
	92 EQUIPMENT (Food)		05 DESICCANT		13 INVERT EMULSION
	93 EQUIPMENT (Agricultural)		06 FEEDING DEPRESSANT		14 FLOWABLE CONCENTRATE
	94 EQUIPMENT (Medical)		07 GROWTH INHIBITOR	X	15 SOLUBLE CONCENTRATE
	95 EQUIPMENT (Transportation)		08 GROWTH REGULATOR		16 SOLUTION (Ready to Use)
	96 LAUNDRY AND DRY CLEANING		09 POISON (Single dose)		17 OILS (No added pesticide)
	97 INDUSTRIAL PRESERVATIVES		10 POISON (Multiple Dose)		18 PRESSURIZED (Gas)
	98 PESTICIDE (Manufacturing only)		11 PRESERVATIVE		19 PRESSURIZED (Liquid)
	99 OTHER (Specify)		12 REPELLENT		20 PRESSURIZED (Dust)
			13 OTHER (Specify)		21 OTHER (Specify)

REMARKS

This product is for reformulation use only.

EPA Form 8570-10 (11-74)

Registration Number

524-339

Pages 362-364 Confidential Statement of Formula may be entitled to confidential treatment

CHEMICAL NAME/PESTICIDE CHEMICAL CODE (PCC) REQUEST FORM*

CR#: 95-0369

REQUESTOR NAME: Sami Malak REQUEST DATE: 7/26/95
TEL.:(703) 308-8392 ORG.: PCRSI/RSB/RF (DIV./BR./SEC.) ROOM: 605 MAIL CODE: H7505W

CSF ATTACHED:
- ☒ YES If CSF is attached complete Item A and the chemical name in Item B.
- ☐ NO If CSF is not attached complete Items A through C.

A. INFORMATION REQUIRED:
✓Check Applicable Category
- ☐ Provide PCC and Tolerance Exemption Status For Food-Use Inert Ingredient(s)
- ☒ Provide PCC for Non-Food Use Inert Ingredient (s)
- ☐ Provide PCC for Active Ingredient(s)
- ☐ Provide PCC for Dye
- ☐ Determine if Fragrance is Acceptable for Use in Formulation
- ☐ Other (Describe): _____

B. INGREDIENT INFORMATION:

Ingredient No. 1:
Chem. Name: None
Trade Name: [redacted]
CAS Reg. No.: None

Ingredient No. 2:
Chem. Name:
Trade Name:
CAS Reg. No.:

Ingredient No. 3:
Chem. Name:
Trade Name:
CAS Reg. No.:

Ingredient No. 4:
Chem. Name:
Trade Name:
CAS Reg. No.:

C. PESTICIDE PRODUCT INFORMATION:

EPA Reg. No./File Symbol: 524-339 Product Name: Sharpshle C Herbicide
Registrant: Monsanto Company Food-Use Pesticide: ☐ YES ☒ NO
Percent in Formulation (For Fragrance/Dyes only): 42

INFORMATION REPORTED:

Ingredient No. 1:
PCC: [redacted]
TOL. STATUS:
OTHER INF.:

Ingredient No. 2:
PCC:
TOL. STATUS:
OTHER INF.:

Ingredient No. 3:
PCC:
TOL. STATUS:
OTHER INF.:

Ingredient No. 4:
PCC:
TOL. STATUS:
OTHER INF.:

Completed By: LINDA FAN Date Completed: 07/27/95

Once completed, this form may be entitled to treatment as CBI under section 10 of FIFRA. If so, a red FIFRA CBI cover should be affixed to the request form and the document handled accordingly.

Inert ingredient information may be entitled to confidential treatment

Pages 366-367 Confidential Statement of Formula may be entitled to confidential treatment

524-339

Ref #	action code		Appl date
15	660	Seedling Germination/Seedling Emergence	4/10/87
16	660	Citrus Fruit Dmg	4/10/87

524-339

Ref #	Act code	Description	Date
1	300	add bulk label	8/21/81
2	161	Reselenssion	5/17/83
3	400	acutotoxes Tests	9/14/83
4	305 [redacted]	Inhalation / Dermal Tests	12/23/84
5	300	Update 22° Disposal	12/11/84
6	300	Update 54 gal & Bulk Container Label	11/11/85
7	300	Update Storage & Disposal + Bulk Container Label	10-17-86
8	660	Reply to RCB [redacted] & PC Standard Comments	11/7/86
9	660	Reply to TB Comments and Mouse Study	11/7/86
10	655	Ref Dermal Sensitization Study	11/7/86
11	660	Reply to EAB Comments	11/7/86
12	660	Protocols for RCB-EAB Studies Reply to	12/22/86
13	655	Request to Relate Weber Letter Rules Requirement	2/9/87
14	660	Request to do Vegetative Vigor Study	3/6/87

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Confidential Statement of Formula may be entitled to confidential treatment